

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

UNITED STATES OF AMERICA, ) CR-18-00258-EJD  
)  
PLAINTIFF, )  
) SAN JOSE, CALIFORNIA  
VS. )  
) JANUARY 13, 2020  
ELIZABETH A. HOLMES AND RAMESH )  
SUNNY BALWANI, ) PAGES 1 - 46  
)  
DEFENDANTS. ) **SEALED PAGES 41 - 44**  
)  
\_\_\_\_\_ )

TRANSCRIPT OF PROCEEDINGS  
BEFORE THE HONORABLE EDWARD J. DAVILA  
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE  
BY: JOHN C. BOSTIC  
JEFFREY B. SCHENK  
150 ALMADEN BOULEVARD, SUITE 900  
SAN JOSE, CALIFORNIA 95113  
  
BY: ROBERT S. LEACH  
VANESSA BAEHR-JONES  
1301 CLAY STREET, SUITE 340S  
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTER:

IRENE L. RODRIGUEZ, CSR, RMR, CRR  
CERTIFICATE NUMBER 8074

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY  
TRANSCRIPT PRODUCED WITH COMPUTER

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

A P P E A R A N C E S: (CONT 'D)

FOR DEFENDANT HOLMES: WILLIAMS & CONNOLLY LLP  
BY: KEVIN M. DOWNEY  
LANCE A. WADE  
KATHERINE A. TREFZ  
725 TWELFTH STREET, N.W.  
WASHINGTON, D.C. 20005

LAW OFFICE OF JOHN D. CLINE  
BY: JOHN D. CLINE  
ONE EMBARCADERO CENTER, SUITE 500  
SAN FRANCISCO, CALIFORNIA 94111

FOR DEFENDANT BALWANI: ORRICK, HERRINGTON & SUTCLIFFE LLP  
BY: WALTER F. BROWN, JR.  
RANDALL LUSKEY  
THE ORRICK BUILDING  
405 HOWARD STREET  
SAN FRANCISCO, CALIFORNIA 94105

BY: STEPHEN A. CAZARES  
SUITE 3200  
777 SOUTH FIGUEROA STREET  
LOS ANGELES, CALIFORNIA 90017

FOR THE FDA: UNITED STATES SECURITIES AND EXCHANGE  
COMMISSION  
BY: MARCI NORTON  
JACKIE MARTINEZ-RESLY  
DOUG WEINFELD

TELEPHONICALLY: BY: STACY AMIN  
PERHAM GORGI

1 SAN JOSE, CALIFORNIA

JANUARY 13, 2020

2 P R O C E E D I N G S

3 (COURT CONVENED AT 10:05 A.M.)

4 THE COURT: LET'S CALL 18-258, UNITED STATES VERSUS  
5 HOLMES, BALWANI.

6 IF I COULD CAPTURE THE APPEARANCES OF THE PARTIES, PLEASE.

7 MR. LEACH: THANK YOU, YOUR HONOR. GOOD MORNING.

8 ROBERT LEACH FOR THE UNITED STATES. TO MY LEFT IS  
9 JEFF SCHENK, JOHN BOSTIC, AND I WANTED TO ESPECIALLY INTRODUCE  
10 VANESSA BAEHR-JONES WITH MY OFFICE. SHE FILED A NOTICE OF  
11 APPEARANCE A MONTH OR TWO AGO, BUT THIS IS HER FIRST LIVE  
12 APPEARANCE BEFORE YOU.

13 THE COURT: THANK YOU. GOOD MORNING.

14 MS. BAEHR-JONES: GOOD MORNING, YOUR HONOR.

15 MR. WADE: GOOD MORNING, YOUR HONOR. LANCE WADE  
16 FROM WILLIAMS & CONNOLLY FOR MS. HOLMES. WITH ME FROM MY FIRM  
17 ARE MY COLLEAGUES, KEVIN DOWNEY AND KATHERINE TREFZ.

18 THE COURT: THANK YOU.

19 MR. WADE: AS WELL AS COCOUNSEL, JOHN CLINE. AND  
20 MS. HOLMES IS PRESENT.

21 THE COURT: THANK YOU. GOOD MORNING.

22 MR. CAZARES: GOOD MORNING, YOUR HONOR.  
23 STEPHEN CAZARES AND WALT BROWN FOR MR. BALWANI WHO IS NOT  
24 PRESENT.

25 THE COURT: AND REMIND ME AGAIN ABOUT HIS ABSENCE.

10:06AM 1 MR. WADE: MR. BALWANI IS, ALONG WITH MY COCOUNSEL,  
10:06AM 2 MR. COOPERSMITH, ARE ATTENDING DEPOSITIONS IN THE PARALLEL  
10:06AM 3 S.E.C. CASE IN WASHINGTON, D.C.

10:06AM 4 THE COURT: I SEE. OKAY. ALL RIGHT. I THINK THE  
10:07AM 5 GOVERNMENT HAD NOTICE OF THIS. WEREN'T YOU AWARE OF THIS?

10:07AM 6 MR. SCHENK: WE FOUND OUT FRIDAY AFTERNOON, YOUR  
10:07AM 7 HONOR, YES.

10:07AM 8 THE COURT: THANK YOU. THIS MATTER IS ON THIS  
10:07AM 9 MORNING FOR A STATUS CONFERENCE, AND THERE HAS BEEN SOME  
10:07AM 10 FILINGS BY THE GOVERNMENT REGARDING THE DISCOVERY.

10:07AM 11 AND I DID CAPTURE YOU AND I HAVE READ AND REVIEWED YOUR  
10:07AM 12 JOINT STATEMENT. THANK YOU FOR THAT.

10:07AM 13 IS THERE ANYTHING THAT ANYONE WISHES TO ADD TO YOUR JOINT  
10:07AM 14 STATEMENT, UPDATE ME ON ANYTHING THAT HAS CHANGED?

10:07AM 15 APPARENTLY NOT.

10:07AM 16 MR. LEACH: NOTHING THAT HAS CHANGED, YOUR HONOR.  
10:07AM 17 THERE WERE SOME ARGUMENTS THAT I WOULD LIKE TO MAKE WITH  
10:07AM 18 RESPECT TO THE MOTION, BUT I DON'T THINK WE HAVE ANY UPDATE ON  
10:07AM 19 WHAT WAS INCLUDED IN THE JOINT STATUS.

10:07AM 20 THE COURT: OKAY. ALL RIGHT. SO AS I UNDERSTAND  
10:07AM 21 IT -- EXCUSE ME. DO WE HAVE ANY APPEARANCES TELEPHONICALLY?  
10:07AM 22 LET'S CAPTURE THOSE.

10:07AM 23 IS ANYONE PARTICIPATING TELEPHONICALLY? IF YOU COULD,  
10:08AM 24 COULD YOU PLEASE STATE YOUR APPEARANCE.

10:08AM 25 MS. AMIN: YOUR HONOR, MY NAME IS STACY AMIN. I'M

10:08AM 1 THE CHIEF COUNSEL AT THE FOOD AND DRUG ADMINISTRATION.

10:08AM 2 THE COURT: THANK YOU. GOOD MORNING. THANK YOU FOR

10:08AM 3 JOINING US.

10:08AM 4 MR. GORGI: HELLO. THIS IS PERHAM GORGI. I'M

10:08AM 5 DEPUTY CHIEF COUNSEL FOR LITIGATION AT THE FDA OFFICE OF CHIEF

10:08AM 6 COUNSEL.

10:08AM 7 THE COURT: THANK YOU. THANK YOU FOR JOINING US.

10:08AM 8 IS THERE ANYONE ELSE PRESENT TODAY FROM THE FDA?

10:08AM 9 MR. LEACH: YES, YOUR HONOR. I INTENDED TO

10:08AM 10 INTRODUCE THEM DURING MY REMARKS, BUT WE ALSO HAVE THREE

10:08AM 11 ATTORNEYS FROM THE FDA IN WASHINGTON, D.C. HERE WITH US:

10:08AM 12 MARCI NORTON, SENIOR COUNSEL; JACKIE MARTINEZ-RESLY, ALSO WITH

10:08AM 13 THE OFFICE OF CHIEF COUNSEL; AND DOUG WEINFELD, WHO IS AN

10:08AM 14 E-DISCOVERY LAWYER WITHIN THE FDA OFFICE OF CHIEF COUNSEL.

10:08AM 15 THEY'VE COME OUT HERE FROM WASHINGTON FOR THIS HEARING.

10:08AM 16 THE COURT: WELL, GREAT. THANK YOU. GREAT.

10:08AM 17 WELCOME TO CALIFORNIA. I KNOW YOU'LL ENJOY THE WEATHER HERE.

10:08AM 18 I THINK WE SPOKE TELEPHONICALLY AT OUR LAST HEARING,

10:08AM 19 MS. MARTINEZ-RESLY AND MS. NORTON, IF I AM NOT MISTAKEN?

10:09AM 20 MS. NORTON: CORRECT.

10:09AM 21 MS. MARTINEZ-RESLY: CORRECT.

10:09AM 22 THE COURT: THANK YOU. LET'S SEE, BEFORE WE MOVE

10:09AM 23 INTO THE MOTION, AND THIS IS THE GOVERNMENT'S MOTION TO EXTEND

10:09AM 24 TIME I BELIEVE IT IS.

10:09AM 25 AND THIS IS -- WELL, I HAD THE DOCKET LIST HERE.

10:09AM 1 MR. LEACH: YOUR HONOR, THE MOTION IS ECF 215.

10:09AM 2 THE COURT: THANK YOU. LET ME -- I DO WANT TO ASK  
10:09AM 3 ABOUT WHAT THE STATUS OF THINGS ARE.

10:09AM 4 YOU INDICATED IN YOUR MOTION THAT THERE WAS TRAVEL BY  
10:09AM 5 MR. BOSTIC, I THINK, YOURSELF AND MR. SCHENK TO WASHINGTON,  
10:09AM 6 D.C. AND BALTIMORE IN EFFORTS TO DISCUSS MATTERS.

10:09AM 7 WHY DON'T YOU COME FORWARD AND UPDATE ME AND UPDATE US ON  
10:09AM 8 THAT.

10:10AM 9 MR. LEACH: THANK YOU, YOUR HONOR. FIRST, LET ME  
10:10AM 10 EXPLAIN A LITTLE BIT WHY YOU'RE HEARING FROM ME AND NOT  
10:10AM 11 MR. BOSTIC WHO HAS BEEN LEADING THE CHARGE FOR THE GOVERNMENT  
10:10AM 12 ON THIS PREVIOUSLY.

10:10AM 13 MR. BOSTIC WAS IN TRIAL AT THE TIME WHEN THE COURT ISSUED  
10:10AM 14 ITS NOVEMBER 5TH ORDER. HE WAS APPEARING BEFORE JUDGE KOH, SO  
10:10AM 15 AT THE TIME THE COURT RULED THAT THE GOVERNMENT HAD KNOWLEDGE  
10:10AM 16 AND ACCESS TO THESE FDA DOCUMENTS. THE TASK FELL TO ME TO WORK  
10:10AM 17 TO COMPLY WITH THAT ORDER AS EXPEDITIOUSLY AS POSSIBLE.

10:10AM 18 SO WE'RE ONE TEAM. WE HAVE THE SAME INFORMATION, BUT I AM  
10:10AM 19 NOT JOHN BOSTIC, AND I JUST WANTED TO LET YOU KNOW WHY I'M  
10:10AM 20 ADDRESSING THE COURT ON THESE ISSUES TODAY.

10:10AM 21 THE COURT: OKAY. WELL, THANK YOU.

10:10AM 22 MR. LEACH: WE ALSO HAVE ON THE PHONE, I JUST WANT  
10:10AM 23 TO MAKE SURE THE COURT UNDERSTANDS, WE HAVE STACY AMIN, WHO IS  
10:10AM 24 THE CHIEF COUNSEL FOR THE FOOD AND DRUG ADMINISTRATION, THE  
10:10AM 25 SENIOR LAWYER FOR THE FDA, HER DEPUTY CHIEF COUNSEL,

10:10AM 1 PERHAM GORGI, AND THE THREE ATTORNEYS STANDING BEHIND ME WHO I  
10:11AM 2 HAVE INTRODUCED.

10:11AM 3 THEY'RE HERE TODAY TO UNDERScore THE SERIOUSNESS WITH  
10:11AM 4 WHICH THE FDA IS TAKING THIS ISSUE AND TO UNDERScore THE  
10:11AM 5 EFFORTS THAT THEY ARE TAKING TO COMPLY WITH THE COURT'S  
10:11AM 6 NOVEMBER 5TH AND ITS PRIOR ORDERS.

10:11AM 7 AS I MENTIONED, SINCE THE NOVEMBER 5TH ORDER, YOUR HONOR,  
10:11AM 8 THE GOVERNMENT HAS SPENT A SIGNIFICANT AMOUNT OF TIME WRESTLING  
10:11AM 9 WITH THE QUESTION OF HOW TO GET THESE DOCUMENTS PRODUCED.

10:11AM 10 AS YOU ALLUDED TO, MR. SCHENK AND I TRAVELLED BACK TO  
10:11AM 11 WASHINGTON, D.C. TO MEET BOTH THE FDA, TO MEET WITH CMS TO COME  
10:11AM 12 UP WITH A PLAN TO MAKE SURE THAT THESE DOCUMENTS ARE GETTING  
10:11AM 13 PRODUCED.

10:11AM 14 AND AS PREPARING FOR THE HEARING TODAY, WHAT WAS STRIKING  
10:11AM 15 TO ME IS THE AMOUNT OF COMMON GROUND THERE ACTUALLY IS WITH THE  
10:11AM 16 PARTIES ON THIS ISSUE.

10:11AM 17 THE GOVERNMENT REQUESTED THESE DOCUMENTS BE PRODUCED  
10:11AM 18 VOLUNTARILY. THE DEFENDANT REQUESTED THESE DOCUMENTS BE  
10:11AM 19 PRODUCED. THE FDA IS SAYING THAT IT WANTS TO PRODUCE THESE  
10:12AM 20 DOCUMENTS, AND THE ONLY ISSUE NOW IS A MECHANICAL ONE, I THINK,  
10:12AM 21 HOW WE CAN GET THIS DATA AS QUICKLY AS WE CAN OUTSIDE OF THE  
10:12AM 22 FDA TO THE DEFENDANTS.

10:12AM 23 THE COURT: SOME TIME BEFORE APRIL 30TH, IS THAT  
10:12AM 24 WHAT YOU'RE GOING TO CONCLUDE?

10:12AM 25 MR. LEACH: THAT'S WHERE I'M GOING, YOUR HONOR.

10:12AM 1 THE COURT: GREAT.

10:12AM 2 MR. LEACH: AND I WANT TO EXPLAIN A LITTLE BIT ABOUT  
10:12AM 3 WHY THAT IS THE CASE.

10:12AM 4 I THINK THE ISSUE HERE IS WITH -- THE COURT'S ORDER  
10:12AM 5 REQUIRES ESSENTIALLY A RECOLLECTION OF DOCUMENTS BY THE FDA.

10:12AM 6 WHEN THE FDA STARTED TO PRODUCE DOCUMENTS IN RESPONSE TO  
10:12AM 7 THE S.E.C. SUBPOENA IN THE S.E.C. CASE, AND THEN THE MOTION TO  
10:12AM 8 COMPEL, FOR REASONS THAT I THINK ARE PERFECTLY DEFENSIBLE, IT  
10:12AM 9 DID NOT INCLUDE THIS TERM CALLED LDT. THERE WAS GOOD REASON  
10:12AM 10 FOR THAT. IT WASN'T LISTED IN THE SIX CATEGORIES. ALL OF THE  
10:12AM 11 DOCUMENTS APPEAR TO BE RELATED TO THERANOS.

10:12AM 12 SO WHEN THEY WERE GOING TO THEIR CUSTODIANS AND COLLECTING  
10:13AM 13 DOCUMENTS, THEY ARE NOT LOOKING FOR DOCUMENTS WITH THE TERM  
10:13AM 14 LDT.

10:13AM 15 THEY WERE LOOKING FOR DOCUMENTS RELATING TO THERANOS.  
10:13AM 16 THEY WERE LOOKING FOR DOCUMENTS RESPONSIVE TO THE SIX  
10:13AM 17 CATEGORIES, BUT THIS TERM "LDT" WAS NOT SOMETHING THAT THEY  
10:13AM 18 WERE LOOKING FOR IN THE FIRST INSTANCE.

10:13AM 19 THE COURT'S ORDER RESOLVED THAT ISSUE. WE ACKNOWLEDGED  
10:13AM 20 THE COURT'S ORDER. WE ACKNOWLEDGE THESE DOCUMENTS ARE -- THAT  
10:13AM 21 THE PROSECUTION OF KNOWLEDGE AND ACCESS TO THEM, BUT  
10:13AM 22 ESSENTIALLY WHAT WE'VE BEEN DOING IS RECOLLECTING FROM OVER 88  
10:13AM 23 CUSTODIANS TO TRY TO GET THE RIGHT UNIVERSE OF DOCUMENTS TO  
10:13AM 24 MAKE SURE THAT THEY'RE BEING PRODUCED, AND THAT IS NO SMALL  
10:13AM 25 FEAT, YOUR HONOR.



10:13AM 1 THAT REQUIRES, YOU KNOW, A TECHNICAL EXTRACTION FROM THE  
10:13AM 2 FDA'S E-MAIL SYSTEM. THEY HAD A LIMITED LICENSE CAPACITY IN  
10:13AM 3 ORDER TO DO THAT. THAT HAS BEEN FIXED, AND NOW THINGS ARE  
10:13AM 4 MOVING A LITTLE BIT MORE QUICKLY.

10:13AM 5 IN ADDITION, WITH RESPECT TO NETWORK FILES, THERE'S A  
10:13AM 6 PARTICULAR SOFTWARE THAT THE FDA USES THAT HAS ITS OWN LIMITS,  
10:14AM 7 AND ON OUR TRIP BY MR. SCHENK AND BACK TO THE FDA WE ASKED,  
10:14AM 8 WELL, ARE THERE RESOURCES THAT THE DOJ CAN GIVE TO HELP YOU  
10:14AM 9 SOLVE THIS PROBLEM OR ARE THERE MORE PEOPLE THAT WE CAN SEND?

10:14AM 10 AND THE RESPONSE I'M GETTING IS NO, THAT THIS IS  
10:14AM 11 COMPLICATED SOFTWARE, THAT IT REQUIRES A LENGTHY INSTALLATION  
10:14AM 12 THAT IS INTEGRATED WITH THE FDA SYSTEM, THE FDA HAS ITS OWN  
10:14AM 13 NETWORK CAPACITY.

10:14AM 14 AND I --

10:14AM 15 THE COURT: PARDON ME FOR INTERRUPTING YOU,  
10:14AM 16 MR. LEACH.

10:14AM 17 SO YOU HAD OFFERED BODIES --

10:14AM 18 MR. LEACH: I DID, YOUR HONOR.

10:14AM 19 THE COURT: -- TO GO TO THE FDA AND ASSIST IN  
10:14AM 20 CULLING THIS INFORMATION?

10:14AM 21 MR. LEACH: I DID, YOUR HONOR, YES.

10:14AM 22 THE COURT: OKAY. THANK YOU.

10:14AM 23 MR. LEACH: IN ADDITION, THE DOJ IS THROWING A LOT  
10:14AM 24 OF BODIES, INCLUDING ME, INCLUDING MR. SCHENK, AND INCLUDING  
10:14AM 25 MR. BOSTIC, AND ACTUALLY DOING SOME OF THE REVIEW OF THE DATA

10:14AM 1 THAT WE ARE GETTING FROM THE FDA.

10:14AM 2 SO I DON'T WANT TO STAND UP HERE AND LEAVE THE IMPRESSION  
10:14AM 3 THAT THE DOJ IS NOT THROWING TREMENDOUS RESOURCES AT THIS. WE  
10:15AM 4 ARE. BUT THERE ARE SOME TECHNICAL ISSUES AT THE HEART OF THIS  
10:15AM 5 WHERE IN ORDER FOR DOJ TO REVIEW THIS, WE NEED TO EXTRACT IT  
10:15AM 6 FROM THE E-MAIL SYSTEM USING THE TERMS THAT WERE NOW AGREED  
10:15AM 7 UPON WITH THE DEFENSE. AND EVERY DAY I ASK THE QUESTION, WHY  
10:15AM 8 CAN'T THAT GO FASTER? AND THE ANSWER, UNFORTUNATELY, IS SIMPLY  
10:15AM 9 NOT ENOUGH LICENSES WITHIN THE FDA, INSTALLATION OF MORE WILL  
10:15AM 10 TAKE A LOT OF TIME AND IS INTERTWINED WITH THE FDA NETWORK.

10:15AM 11 AND THERE JUST WAS NOT A GOOD TECHNOLOGICAL SOLUTION TO  
10:15AM 12 THAT.

10:15AM 13 THE GOOD NEWS, YOUR HONOR, IS WE'VE RECEIVED -- DOJ HAS  
10:15AM 14 RECEIVED THREE TRANCHES OF DATA FROM FDA FROM THE E-MAIL  
10:15AM 15 COLLECTION. I'VE LOST TRACK OF THE EXACT NUMBER OF CUSTODIANS,  
10:15AM 16 BUT I THINK IT'S SOMEWHERE IN THE NEIGHBORHOOD OF 25 TO 30, AND  
10:15AM 17 I THINK AN ADDITIONAL 10 WILL BE COMPLETED SOME TIME WITHIN THE  
10:15AM 18 NEXT WEEK OR SO.

10:15AM 19 THERE'S ALSO NETWORK DATA THAT NEEDS TO BE EXTRACTED, AND  
10:16AM 20 THERE'S ALSO THESE ARCHIVED CUSTODIANS THAT NEED TO BE RESTORED  
10:16AM 21 AND THEN DELIVERED TO DOJ FOR REVIEW.

10:16AM 22 AND I WANT TO EMPHASIZE, THIS IS A RESULT OF IN PART  
10:16AM 23 RE-COLLECTING FOR THIS TERM LDT, WHICH I THINK THE FDA HAD  
10:16AM 24 DEFENSIBLE REASONS FOR NOT INCLUDING IN ITS INITIAL COLLECTION,  
10:16AM 25 BUT WE ARE WHERE WE ARE ON THAT ISSUE, YOUR HONOR, AND THE

10:16AM 1 COURT HAS RULED ON IT AND WE'VE ACCEPTED THAT.

10:16AM 2 WE'RE TRYING AS QUICKLY AS WE CAN TO MAKE THAT  
10:16AM 3 RE-COLLECTION HAPPEN AS QUICKLY AS IT CAN HAPPEN.

10:16AM 4 WE'VE PRODUCED OVER 130,000 DOCUMENTS TO THE DEFENDANTS  
10:16AM 5 PRIOR TO -- ON DECEMBER 21ST, 2019, IN COMPLIANCE WITH THE  
10:16AM 6 COURT'S ORDER. I NOW HAVE SOMETHING IN THE MAGNITUDE OF 400  
10:16AM 7 GIGABYTES OF DATA AT THE DOJ THAT WE ARE LOOKING THROUGH AND  
10:16AM 8 ANTICIPATING MAKING ANOTHER PRODUCTION IN THE NEXT WEEK OR TWO.

10:17AM 9 SO WE ARE MOVING JUST ABSOLUTELY AS FAST AS WE CAN. AND I  
10:17AM 10 WANT TO EMPHASIZE THAT THERE IS AN ELEMENT OF DIMINISHING  
10:17AM 11 RETURNS ON THESE DOCUMENTS THAT WE'RE PRODUCING. I DON'T WANT  
10:17AM 12 TO MINIMIZE THE IMPORTANCE OF DOING THE SEARCH RIGHT, BECAUSE  
10:17AM 13 WE ARE DOING THE SEARCH RIGHT.

10:17AM 14 BUT THERE ARE 88 CUSTODIANS THAT WE'RE LOOKING FOR HERE,  
10:17AM 15 YOUR HONOR. A HANDFUL OF THESE WITNESSES AT BEST ARE EVER  
10:17AM 16 GOING TO STEP FOOT IN THIS COURTROOM. IT IS NOT OUR INTENTION  
10:17AM 17 TO DROP HUNDREDS OF THOUSANDS OF DOCUMENTS ON THE DEFENDANTS ON  
10:17AM 18 APRIL 30TH. THAT IS NOT WHAT WE ARE TRYING TO DO.

10:17AM 19 WE ARE TRYING TO MOVE AS QUICKLY AS WE CAN AND BUILD IN A  
10:17AM 20 REALISTIC TIMETABLE WHERE I HOPE BY APRIL 30TH, OR SHORTLY  
10:17AM 21 AFTER THAT, IT'S THE LAST FEW CUSTODIANS THAT ARE COMING IN,  
10:17AM 22 BUT THESE ARE NOT DOCUMENTS THAT HAVEN'T BEEN IN SOMEBODY  
10:17AM 23 ELSE'S FILE OR SEEN SOMEWHERE ELSE, AND I AM NOT  
10:17AM 24 REVOLUTIONIZING THE CASE FOR LACK OF A BETTER WORD.

10:17AM 25 BUT THAT'S WHAT WE'RE DOING.

10:18AM 1 THE DEFENSE RESPONSE TO THIS IS ESSENTIALLY MOVE FASTER,  
10:18AM 2 AND THE GOVERNMENT HAS MET AND SPENT A LOT OF TIME TRYING TO  
10:18AM 3 MAKE THIS MOVE AS QUICKLY AS WE CAN.

10:18AM 4 AS I HAVE EMPHASIZED, WE HAVE ALREADY PRODUCED 130,000  
10:18AM 5 DOCUMENTS BETWEEN NOVEMBER 5TH AND DECEMBER 31ST.

10:18AM 6 THE COURT: APPARENTLY THEY'RE SPEED READERS AND  
10:18AM 7 THEY FINISHED GOING THROUGH THAT AND THEY NEED MORE WORK.

10:18AM 8 MR. LEACH: I'M DOING WHAT I CAN THERE.

10:18AM 9 THE COURT: WE'LL HEAR FROM THEM A MOMENT.

10:18AM 10 I APPRECIATE THAT. BUT YOU ALSO INDICATE IN YOUR  
10:18AM 11 PLEADINGS THAT IN AN EFFORT TO GAIN EFFICIENCY IN THE  
10:18AM 12 PRODUCTION, YOU HAVE WORKED, I THINK, WITH THE DEFENSE TO  
10:18AM 13 IDENTIFY MORE CRITICAL WITNESSES AND INFORMATION AND YOU HAVE  
10:18AM 14 FOCUSED ON ACCOMPLISHING AND RELEASING THAT IN A PRIORITY TYPE  
10:18AM 15 OF MANNER.

10:18AM 16 MR. LEACH: I THINK QUITE COLLABORATIVELY, YOUR  
10:18AM 17 HONOR. I'LL LET THEM SPEAK TO THAT. BUT THERE'S AGREEMENT ON  
10:18AM 18 THE TERMS THAT SHOULD BE USED TO DO THIS RE-COLLECTION.

10:19AM 19 THE DEFENSE HAS AGREED TO AN ORDER REQUIRING THE FDA TO  
10:19AM 20 PRODUCE CERTAIN DOCUMENTS AND NOTWITHSTANDING STATUTORY  
10:19AM 21 PROHIBITIONS ON US DOING THAT; AND, THEREFORE, ENABLING THE DOJ  
10:19AM 22 TO CONDUCT THE REVIEW. SO I THINK THERE HAS BEEN COLLABORATION  
10:19AM 23 ON THAT.

10:19AM 24 I WOULD ALSO EMPHASIZE THAT THEY VERY HELPFULLY GAVE US A  
10:19AM 25 LIST OF THE 22 MOST IMPORTANT CUSTODIANS IN THEIR MIND, AND WE

10:19AM 1 HAVE PRIORITIZED THOSE. I THINK THE E-MAIL FILES FOR ALL OF  
10:19AM 2 THE ACTIVE ONES ARE AT LEAST NOW IN DOJ'S POSSESSION AND WILL  
10:19AM 3 BE GOING OUT SHORTLY.

10:19AM 4 THE COURT: SO GOING OUT SHORTLY MEANING YOU'LL BE  
10:19AM 5 ABLE TO RELEASE THOSE 22?

10:19AM 6 MR. LEACH: I NEED TO BE CAREFUL, YOUR HONOR,  
10:19AM 7 BECAUSE THERE ARE SOME FORMER EMPLOYEES THAT I DON'T THINK I  
10:19AM 8 HAVE YET. WHEN I SIT DOWN I CAN CHECK ON THAT DETAIL.

10:19AM 9 BUT IF THEY'RE A CURRENT FDA EMPLOYEE, WE WILL HAVE ALL OF  
10:19AM 10 THE E-MAIL DATA. IF I DON'T ALREADY HAVE IT, IT'S GOING TO BE  
10:19AM 11 THIS WEEK, AND THAT WILL BE GOING OUT VERY SHORTLY.

10:19AM 12 THE COURT: TO THEM?

10:19AM 13 MR. LEACH: YES. OH, YES.

10:19AM 14 THE COURT: SO LET ME ASK YOU A LARGE OVERARCHING  
10:20AM 15 QUESTION PERHAPS, WHICH IS IF WE WAIT UNTIL APRIL 30TH, THE  
10:20AM 16 COURT SAYS I APPRECIATE YOUR EFFORTS, AND I DO, LET ME JUST SAY  
10:20AM 17 THAT, I DO APPRECIATE. SENDING LAWYERS OUT TO WASHINGTON, D.C.  
10:20AM 18 IN JANUARY IS A REMARKABLE THING TO DO. AND YOU'VE MET YOUR  
10:20AM 19 DECLARATION.

10:20AM 20 YOUR BRIEFING TELLS US THAT YOU'VE MET IN BALTIMORE AND IN  
10:20AM 21 WASHINGTON, D.C. WITH THE APPROPRIATE PARTIES. MY SENSE IS  
10:20AM 22 THAT YOU'VE URGED THEM, YOU'VE EXPRESSED THE URGENCY OF THIS  
10:20AM 23 COURT'S ORDER AND WHAT THAT MEANS AND THE NEED FOR THIS  
10:20AM 24 INFORMATION FOR THIS PARTICULAR LITIGATION.

10:20AM 25 MY QUESTION IS IF WE WAIT UNTIL APRIL 30TH, WHAT IS YOUR

10:20AM 1 POSITION ON WHETHER OR NOT THAT WILL DISTURB THE TRIAL DATE?

10:20AM 2 MR. BOSTIC: IT WILL NOT DISTURB THE TRIAL DATE FROM  
10:20AM 3 THE GOVERNMENT'S PERSPECTIVE, YOUR HONOR. WE ARE NOT ASKING  
10:20AM 4 FOR MORE TIME.

10:20AM 5 THESE ARE NOT DOCUMENTS THAT THE GOVERNMENT EXPECTS TO BE  
10:21AM 6 USING IN ITS CASE-IN-CHIEF, AND WE WILL BE PREPARED TO HAVE  
10:21AM 7 REVIEWED THEM AND DIGESTED THEM WITHIN THE TIME ALLOTTED FOR  
10:21AM 8 THE TRIAL DATE. I DON'T KNOW WHAT THE DEFENSE'S POSITION IS.

10:21AM 9 THE COURT: WELL, YOU CAN ANTICIPATE THAT THEY'RE  
10:21AM 10 GOING TO SAY THAT GIVES US 90 DAYS TO GO THROUGH WHATEVER  
10:21AM 11 TERABYTES THIS INFORMATION IS, AND WE CAN'T POSSIBLY DO THAT.

10:21AM 12 AND THEY'LL START TALKING ABOUT THE CONSTITUTION AND THE  
10:21AM 13 SIXTH AMENDMENT AND THE FIFTH AMENDMENT AND OTHERS. AND  
10:21AM 14 THEY'LL SAY, JUDGE, WE NEED MORE TIME TO GO THROUGH THIS. IT'S  
10:21AM 15 NOT FAIR TO UNLOAD THIS WHEELBARROW OF INFORMATION ON US WHILE  
10:21AM 16 WE'RE TRYING TO PREPARE.

10:21AM 17 BUT WHAT YOU'VE SAID IS THAT'S NOT WHAT'S HAPPENING. IT  
10:21AM 18 SOUNDS LIKE THERE'S A ROLLING RELEASE OF INFORMATION AND THE  
10:21AM 19 INFORMATION THAT THEY'RE GETTING IS SUFFICIENT FOR THEM TO  
10:21AM 20 REVIEW NOW.

10:21AM 21 IF YOU GAVE THEM A WHOLE DUMP TRUCK OF INFORMATION NOW, IT  
10:21AM 22 WOULD PROBABLY TAKE THEM BEYOND APRIL 30TH JUST TO READ IT MY  
10:21AM 23 SENSE IS.

10:22AM 24 MR. LEACH: IT ABSOLUTELY IS A ROLLING PRODUCTION,  
10:22AM 25 YOUR HONOR. THE POINT I WOULD LIKE TO MAKE THERE IS THIS IS

10:22AM 1 NOT A SITUATION WHERE IT'S ANYBODY'S INTENTION TO WAIT UNTIL  
10:22AM 2 APRIL 30TH AND SAY, HERE YOU GO, THIS IS THE UNIVERSE OF FDA  
10:22AM 3 DOCUMENTS, REVIEW THEM.

10:22AM 4 WE'RE GETTING AS MUCH AS WE CAN TO THEM AS QUICKLY AS WE  
10:22AM 5 CAN TO THEM.

10:22AM 6 BUT WHEN YOU ASK ME WHEN CAN I BE DONE REVIEWING THE FILES  
10:22AM 7 OF 88 CUSTODIANS AND GOING THROUGH ALL OF THE MECHANICAL ISSUES  
10:22AM 8 THAT WE HAVE TO GO THROUGH TO EXTRACT THAT DATA, GET IT TO DOJ,  
10:22AM 9 GET THE REVIEW DONE, THE BEST I CAN PROMISE ON THAT IS  
10:22AM 10 APRIL 30TH.

10:22AM 11 BUT IT IS NOT OUR INTENTION AT ALL TO WAIT UNTIL THEN TO  
10:22AM 12 PRODUCE AS LARGE A CHUNK AS WE CAN.

10:22AM 13 THE COURT: OKAY. TELL ME WHAT YOU MEAN BY "A  
10:22AM 14 MANUAL SEARCH" FOR marginally relevant custodians?

10:22AM 15 IS THERE A DISCUSSION OR DISPUTE ABOUT A MANUAL SEARCH AS  
10:23AM 16 OPPOSED TO AN ELECTRONIC OR OTHER SEARCH?

10:23AM 17 MR. LEACH: WHAT I MEAN BY THAT, YOUR HONOR, IS IT'S  
10:23AM 18 A SELF-COLLECTION. SO WHAT THE GOVERNMENT'S INTENTION WITH  
10:23AM 19 THOSE 23 INDIVIDUALS IS THAT WE WOULD GIVE THEM THE 6  
10:23AM 20 CATEGORIES OF DOCUMENTS, WE WOULD GIVE THEM A LIST OF SEARCH  
10:23AM 21 TERMS. THOSE SEARCH TERMS WOULD INCLUDE THERANOS, LDT,  
10:23AM 22 FRANKLY, WHATEVER THE DEFENSE WANTS TO INCLUDE ON THAT AND HAS  
10:23AM 23 INCLUDED ON THAT, AND WE WOULD ASK THOSE CUSTODIANS TO PERFORM  
10:23AM 24 THE SEARCH ON THEIR COMPUTER, SO GO INTO YOUR E-MAIL FILE AND  
10:23AM 25 LOOK FOR THE WORD "THERANOS."

10:23AM 1 IF YOU HAVE AN E-MAIL FILE FOR THERANOS, COPY THAT TO THIS  
10:23AM 2 DRIVE SO THE I.T. PROFESSIONALS CAN PROCESS THAT.

10:23AM 3 THE COURT: AND THIS WOULD BE SUPERVISED BY DOJ  
10:23AM 4 INDIVIDUALS?

10:23AM 5 MR. LEACH: DOJ -- WE WILL DO WHATEVER THE COURT  
10:23AM 6 REQUIRES OF US ON THAT POINT, AND I THINK THERE'S SOME, YOU  
10:23AM 7 KNOW, WE'RE NOT -- WE HAVE ACCESS AND KNOWLEDGE OF THESE  
10:24AM 8 DOCUMENTS. I'M NOT HERE TO SAY ANYTHING OTHERWISE.

10:24AM 9 BUT I DON'T WORK IN THE FDA. WHEN I GO TO THE FDA, YOUR  
10:24AM 10 HONOR, I WALK THROUGH THE SECURITY GATE JUST LIKE ANYBODY ELSE.  
10:24AM 11 THEY'RE STATUTORILY PROHIBITED FROM GIVING ME ACCESS TO CERTAIN  
10:24AM 12 INFORMATION, AND SO I WILL NOT BE SITTING OVER THE COMPUTER AS  
10:24AM 13 SOMEBODY DOES THAT, BUT DOJ WILL HAVE SIGNIFICANT INPUT ON THE  
10:24AM 14 SCRIPT OR THE INSTRUCTIONS OR THE DIRECTION THAT THEY WILL BE  
10:24AM 15 GIVEN.

10:24AM 16 AND I NEED TO EMPHASIZE, HALF OF THIS GROUP IS LAWYERS WHO  
10:24AM 17 ARE AS CAPABLE, IF NOT MORE CAPABLE, THAN ME FOR FINDING THESE  
10:24AM 18 DOCUMENTS.

10:24AM 19 I REALLY THINK THAT IN THE DIALOGUE THAT WE WERE HAVING  
10:24AM 20 BEFORE ABOUT DEFICIENCIES IN THE SEARCH, YOU KNOW, I HAVE NO  
10:24AM 21 REASON TO THINK THAT THESE LAWYERS AREN'T PERFECTLY CAPABLE OF  
10:24AM 22 FINDING THE RESPONSIVE DOCUMENTS WITH VERY PRECISE DIRECTIONS  
10:24AM 23 FROM DOJ, SOMETHING IN WRITING, AND SO THAT'S WHAT WE MEAN BY  
10:24AM 24 SELF-COLLECTION AS OPPOSED TO THE ELECTRONIC COLLECTION, WHICH  
10:25AM 25 WE'VE BEEN DOING, WHERE THE FDA'S I.T. TEAM IS GOING INTO



10:25AM 1 OUTLOOK THEMSELVES, RUNNING THE SEARCH TERMS THEMSELVES, TAKING  
10:25AM 2 THAT DATA, AND GIVING IT TO DOJ.

10:25AM 3 SO THERE'S NO REAL JUDGMENT IN ANY OF THAT. BUT THE  
10:25AM 4 SELF-COLLECTION IS, FOR EXAMPLE, IF I GIVE ONE SHEET OF  
10:25AM 5 INSTRUCTIONS TO YOUR HONOR TO GO BACK TO YOUR CHAMBERS AND LOOK  
10:25AM 6 FOR YOUR THERANOS FILE, AND PUT IT HERE, THAT'S WHAT WE MEAN BY  
10:25AM 7 SELF-COLLECTION.

10:25AM 8 THE COURT: ARE YOU SUGGESTING THAT THAT WILL  
10:25AM 9 EXPEDITE THE MANUAL SELF-SELECTION? WILL THAT BE QUICKER OR  
10:25AM 10 WILL THAT BE FASTER THAN THE ELECTRONIC VERSION, OR IS THAT IN  
10:25AM 11 ADDITION TO?

10:25AM 12 MR. LEACH: IT WILL BE QUICKER, IT WILL BE FASTER,  
10:25AM 13 BUT THAT THE -- THAT WITH ELECTRONIC COLLECTION IS STILL GOING  
10:25AM 14 TO TAKE TO BE DONE, DONE, APRIL 30TH.

10:25AM 15 IF THE COURT REQUIRES US TO DO SOMETHING DIFFERENT FOR  
10:26AM 16 THOSE 23, WE'RE LOOKING AT A TIMEFRAME THAT IS EVEN LONGER.

10:26AM 17 THE COURT: I SEE.

10:26AM 18 SO THE QUESTION THAT A PERSON MIGHT ASK IS, WELL, THAT'S  
10:26AM 19 FINE, YOU CAN ASK PEOPLE TO GO TO THEIR COMPUTERS AND DO THIS,  
10:26AM 20 BUT HOW DO WE KNOW? HOW DO WE VERIFY THAT THEY'RE ACTUALLY  
10:26AM 21 DOING THAT?

10:26AM 22 IF A FILE COMES UP AND IT'S SOMETHING THAT THEY MISS OR  
10:26AM 23 THEY MIGHT HAVE SOME QUALMS ABOUT, HOW DO WE KNOW WE'RE GETTING  
10:26AM 24 EVERYTHING?

10:26AM 25 I EXPECT THE DEFENSE MIGHT SAY THERE'S NO ASSURANCE AS FAR

10:26AM 1 AS -- WE'RE JUST RELYING ON THE INDIVIDUAL AS OPPOSED TO AN  
10:26AM 2 ACTUAL REAL ELECTRONIC RECORD OF WHAT WAS DONE.

10:26AM 3 MR. LEACH: THOSE ARE PROBLEMS THAT ARE INHERENT IN  
10:26AM 4 ANY DOCUMENT COLLECTION BY ANYBODY.

10:26AM 5 IF YOU HAVE A CLIENT, YOUR HONOR, AND YOU SAY -- THE  
10:26AM 6 RELATIONSHIP BETWEEN ME AND THE FDA IS DIFFERENT THAN THIS, BUT  
10:26AM 7 I'M USING THIS AS A HYPOTHETICAL FOR YOU.

10:26AM 8 YOU KNOW, IF YOU SAY THE OTHER SIDE HAS ASKED FOR THESE  
10:26AM 9 FIVE DOCUMENTS, I NEED TO GO LOOK THROUGH YOUR FILES TO FIND  
10:27AM 10 THIS, AND THEY SHOW YOU THE FILES, BUT THEN THEY REMEMBER THAT  
10:27AM 11 THEY HAVE SOME IN THE GARAGE, LIKE ALL OF THIS IS INHERENTLY  
10:27AM 12 DEPENDENT ON SOME INDIVIDUAL AT THE END OF THE DAY RECEIVING  
10:27AM 13 THIS REQUEST.

10:27AM 14 BUT I'M CONFIDENT ABOUT WHAT THE GOVERNMENT'S RULE 16  
10:27AM 15 OBLIGATION IS THAT IF, WITH THE HELP OF THE DEFENSE WITH THE  
10:27AM 16 FDA'S I.T. PROFESSIONALS, THE FACT THAT THESE ARE VERY  
10:27AM 17 SOPHISTICATED LAWYERS WORKING WITHIN THE OFFICE OF CHIEF  
10:27AM 18 COUNSEL, IF I SAY GO LOOK HERE, GO LOOK THERE, RUN THESE  
10:27AM 19 SEARCHES, NO DISCRETION IN THE SEARCH TERMS, NO DISCRETION IN  
10:27AM 20 WHERE THEY'RE WORKING, THE LIKELIHOOD OF A MATERIAL DOCUMENT  
10:27AM 21 BEING MISSED GOES WAY, WAY DOWN.

10:27AM 22 SO, YOU KNOW, NO SYSTEM IS PERFECT, YOUR HONOR.

10:27AM 23 THE COURT: SURE. EVERYTHING IS SUBJECT TO HUMAN  
10:27AM 24 FOIBLE.

10:27AM 25 BUT I'M JUST CURIOUS, AND I'LL ASK THE DEFENSE ABOUT THIS,

10:27AM 1 IT MAY BE THAT THIS COURT -- AND I'LL ASK MS. AMIN HER OPINION  
10:27AM 2 ABOUT THIS AS WELL -- IT MAY BE THAT THE COURT COULD HAVE THAT  
10:28AM 3 GO FORWARD, THAT MANUAL SEARCH GO FORWARD WITH THIS COURT'S  
10:28AM 4 ORDER TO THE ATTORNEYS WHO ARE DOING THE SEARCH TO DO CERTAIN  
10:28AM 5 THINGS TO MAKE SURE THAT THEY TURN OVER EVERY DOCUMENT, NO  
10:28AM 6 QUESTION ABOUT IT.

10:28AM 7 IN OTHER WORDS, THERE'S NO -- HOW SHALL I SAY? -- JUDGMENT  
10:28AM 8 INVOLVED. IT'S THEY ARE PUSH THE BUTTON, AND PUSH PRINT, OR  
10:28AM 9 WHATEVER IT IS, AND THAT'S IT, AND THEY HAVE NO DISCRETION ON  
10:28AM 10 THAT.

10:28AM 11 DO YOU THINK YOU AND YOUR COLLEAGUE OPPOSITES COULD COME  
10:28AM 12 UP WITH AN ORDER THAT MIGHT SATISFY MS. AMIN, AND MS. NORTON,  
10:28AM 13 AND MS. MARTINEZ-RESLY, AND MR. WEINFELD ABOUT THOSE THINGS?

10:28AM 14 MR. LEACH: YES, YOUR HONOR.

10:28AM 15 THE COURT: OKAY.

10:28AM 16 MR. LEACH: BEFORE I PASS THE MIKE, YOUR HONOR, WE  
10:28AM 17 DID INVITE THE CHIEF COUNSEL FROM THE FDA TO BE PRESENT FOR  
10:28AM 18 THIS HEARING. SHE WANTED VERY MUCH TO BE HERE IN PERSON, BUT  
10:28AM 19 SOME OTHER VERY IMPORTANT DEMANDS GOT IN THE WAY.

10:28AM 20 BUT I DO THINK IT'S IMPORTANT THAT THE COURT HEAR DIRECTLY  
10:28AM 21 FROM MS. AMIN --

10:29AM 22 THE COURT: SURE.

10:29AM 23 MR. LEACH: -- ABOUT THE EFFORTS THAT THE FDA IS  
10:29AM 24 TAKING.

10:29AM 25 THE COURT: WELL, THANK YOU. I'M HAPPY TO DO THAT.

1 MS. AMIN, THANK YOU FOR JOINING US TELEPHONICALLY. YOU'VE  
2 HEARD OUR DISCUSSION AND SOME OF THE QUESTIONS THAT I'VE HAD.  
3 I'M HAPPY TO HEAR FROM YOU NOW IF YOU WOULD LIKE TO SHARE ANY  
4 ITEM WITH US.

5 MS. AMIN: YOUR HONOR, THANK YOU TO GIVING ME THE  
6 OPPORTUNITY TO ADDRESS THE COURT. AND I WANT TO ASSURE YOU  
7 THAT THE FDA IS MAKING EXTRAORDINARY EFFORTS TO COMPLY WITH THE  
8 DOCUMENT PRODUCTION SCHEDULE.

9 THIS IS AN UNPRECEDENTED SITUATION FOR THE FDA. WE HAVE  
10 NEVER BEFORE BEEN SUBJECT TO A DOCUMENT PRODUCTION OF THIS  
11 SCOPE ON THIS TIMEFRAME WHERE WE'RE PRODUCING HUNDREDS OF  
12 THOUSANDS OF PAGES OF DOCUMENTS IN A MATTER OF MONTHS, AND MANY  
13 OF THOSE DOCUMENTS DETAIL SENSITIVE AGENCY DELIBERATIONS AND  
14 CONFIDENTIAL AND COMMERCIAL TRADE SECRET INFORMATION PROTECTED  
15 BY STATUTE.

16 SO IT'S BEEN VERY CHALLENGING AND UNPRECEDENTED THE  
17 SITUATION THAT WE ARE TASKED WITH.

18 AND I WANT TO ASSURE YOU THAT THE LEADERSHIP AT THE  
19 AGENCY, ACROSS THE WHOLE AGENCY AND AT THE HIGHEST LEVEL OF THE  
20 AGENCY ARE ENGAGED IN REGULAR DISCUSSIONS ABOUT HOW TO COMPLY  
21 WITH THE COURT'S SCHEDULE.

22 WE HAVE DEDICATED CAREER CIVIL SERVANTS THAT ARE WORKING  
23 200 PERCENT OF THEIR NORMAL CAPACITY ON THIS, AND WE HAVE  
24 DIVERTED STAFF AND RESOURCES AWAY FROM OTHER HIGH MAJORITY  
25 MISSIONS, SUPPORTIVE TASKS, INCLUDING CRIMINAL INVESTIGATIONS,

1 INJUNCTION REFERRALS, WARNING LETTERS AS EXAMPLES. I CAN'T GET  
2 INTO SPECIFIC PROJECTS, BUT IT'S THE KIND OF WORK THAT SUPPORTS  
3 OUR CRITICAL PUBLIC HEALTH MISSION TO ENSURE THE SAFETY OF THE  
4 FOOD WE EAT AND THE MEDICAL PRODUCTS THAT WE USE, AND SOME OF  
5 THAT WORK HAS TAKEN A BACK SEAT TO THIS DISCOVERY, AND I JUST  
6 TELL YOU THAT TO ILLUSTRATE HOW SERIOUSLY WE ARE TAKING THIS  
7 AND HOW HARD WE ARE TRYING TO MEET THE SCHEDULE.

8 BUT EVEN DESPITE THE EXTRA STAFF AND RESOURCES THAT WE  
9 HAVE DEVOTED AND WE HAVE TAKEN ADVANTAGE OF EVERY OFFER OF  
10 SUPPORT AND RESOURCES THAT DOJ HAS PROVIDED THAT WOULD HELP  
11 SPEED THE PROCESS ALONG, EVEN WITH ALL OF THAT, THERE ARE  
12 TECHNICAL LIMITATIONS TO WHAT WE CAN DO.

13 AND I CAN GO INTO MORE DETAIL ABOUT WHAT THOSE TECHNICAL  
14 LIMITATIONS ARE. THE GOVERNMENT'S COUNSEL HAS HIGHLIGHTED A  
15 FEW OF THEM, BUT I CAN GET INTO MORE DETAIL, AND THERE ARE  
16 REALLY THREE MAJOR LIMITATIONS.

17 FIRST, OUR SOFTWARE HAS LIMITATIONS FOR DOCUMENTS FROM  
18 NETWORK DRIVES. FDA MUST USE THE NK SOFTWARE TO COLLECT,  
19 SEARCH, AND EXPORT THOSE DOCUMENTS AND NK'S CONTRACTORS MUST  
20 HAVE THE SOFTWARE INSTALLED AND BE LICENSED AND TRAINED TO USE  
21 IT.

22 FDA HAS TWO NK LICENSE FOR LITIGATION AND COMPLIANCE. AND  
23 WHAT WE HAVE FOUND IS THAT THE SOFTWARE IS PROHIBITIVELY SLOW  
24 WHEN RUNNING SEARCH STRINGS AT THE SAME TIME THAT WE ARE  
25 COLLECTING.

OUR I.T. STAFF BELIEVES IT WOULD TAKE TOO MUCH TIME TO ONBOARD AND TRAIN MORE CONTRACTORS WITHIN THE TIMEFRAME THAT THIS DISCOVERY NEEDS TO OCCUR, SO WE HAVE ADDRESSED THIS LIMITATION BY EXPORTING DOCUMENTS WITHOUT CONCURRENTLY RUNNING THE SEARCH TERMS, AND INSTEAD DOJ IS NOW GETTING THE NATIVE FILES THEMSELVES AND RUNNING THE SEARCHS THEMSELVES.

AS THE GOVERNMENT COUNSEL JUST EXPLAINED, FOR A SET OF CUSTODIANS WILL BE SELF-COLLECTING SO THAT WE CAN CONCURRENTLY DO BOTH SETS AT THE SAME TIME.

SIMILARLY, WE HAVE LIMITATIONS WITH OUR CONTRACT WITH MICROSOFT OR OUTLOOK 365 WHICH LIMITED HOW MUCH DATA A DAY WE COULD DOWNLOAD AND HOW MANY CONCURRENT SEARCHES WE COULD RUN.

BUT REALLY THE BIGGEST PROBLEM IN OUTLOOK 365 WERE THE ERRORS THAT OCCUR WHEN WE PERFORM CONCURRENT SEARCHES. SO WE ARE NO LONGER PERFORMING SEARCHES IN OUTLOOK AND AS INSTEAD, AS WAS MENTIONED, WE'RE GIVING DOJ THE NATIVE FILES AND DOJ IS RUNNING THE SEARCHES, AND MY UNDERSTANDING IS THAT THEY ARE PUTTING A SIGNIFICANT AMOUNT OF RESOURCES INTO THAT.

AND WE HAVE ALSO ADDRESSED OUR DOWNLOAD LIMITATIONS BY INCREASING OUR CAPACITY WITH MICROSOFT. ALL OF THAT HAS TAKEN TIME TO DO.

THE SECOND MAJOR LIMITATION IS OUR NETWORK BANDWIDTH, WHICH LIMITS HOW MUCH DATA CAN BE EXPORTED AT ANY GIVEN TIME.

WHILE WE CONTINUE TO EXAMINE THE CAUSES OF ANY LIMITATIONS THAT WE HAVE, WE'VE FOUND THAT AS WE HAVE IMPROVED THE

10:33AM 1 EFFICIENCY OF OUR SOFTWARE AND WE CAN MANAGE MORE DOWNLOADS AT  
10:33AM 2 A TIME THROUGH THAT SOFTWARE, WE BELIEVE OUR NETWORK MAY BE  
10:33AM 3 LIMITING HOW MUCH DATA WE CAN EXPORT IN A DAY. OUR NETWORK HAS  
10:33AM 4 TO MANAGE ALL OF THE AGENCY'S TRAFFIC, AND THERE ARE LIMITS ON  
10:33AM 5 HOW MUCH TOTAL TRAFFIC IT CAN ACCOMMODATE BEFORE NETWORK  
10:33AM 6 FUNCTIONS ARE DISRUPTED.

10:33AM 7 SO AT THE HIGHEST LEVEL OF THE AGENCY WE ARE COMMITTED TO  
10:33AM 8 ADDRESSING THIS ISSUE SO THAT GOING FORWARD WE ARE NEVER IN  
10:33AM 9 THIS POSITION AGAIN OF NOT BEING ABLE TO MEET A COURT ORDERED  
10:33AM 10 DEADLINE.

10:33AM 11 THE ADDING NETWORK CAPACITY IS SOMETHING THAT OUR  
10:34AM 12 TECHNICAL EXPERTS HAVE SAID IT CAN'T BE DONE OVERNIGHT OR EVEN  
10:34AM 13 IN A MATTER OF MONTHS. IT'S A MAJOR ENDEAVOR THAT I'VE BEEN  
10:34AM 14 TOLD CAN TAKE 12 TO 18 MONTHS. SO WE'RE WORKING TOWARDS THAT  
10:34AM 15 LONG-TERM SOLUTION, BUT IT'S NOT SOMETHING THAT RIGHT NOW ANY  
10:34AM 16 MONEY OR PEOPLE CAN FIX.

10:34AM 17 SO WHAT WE'RE DOING IN THE MEANTIME IS ADDRESSING THIS, AS  
10:34AM 18 THE GOVERNMENT'S COUNSEL EXPLAINED, CONCURRENTLY HAVING LOWER  
10:34AM 19 PRIORITY CUSTODIANS MANUALLY PULL THEIR RESPONSIVE DOCUMENTS,  
10:34AM 20 AND I CAN PROVIDE A LITTLE BIT MORE DETAIL ABOUT OUR PLAN FOR  
10:34AM 21 DOING THIS. THIS WILL BE DONE IN ACCORDANCE WITH A  
10:34AM 22 SUBCOLLECTION PROTOCOL THAT WILL BE DEVELOPED BY FDA AND DOJ  
10:34AM 23 TOGETHER.

10:34AM 24 WE WILL HAVE AN ATTORNEY FROM FDA WHO WILL LEAD THIS  
10:34AM 25 PROCESS FOR THE AGENCY, AND WE'LL HAVE A TEAM STAFFED BY FOUR

10:34AM 1 OTHER ATTORNEYS AND OTHER COMPLIANCE PROFESSIONALS IN THE  
10:34AM 2 AGENCY, AND THIS TEAM WILL HAND HOLD CUSTODIANS THROUGH THE  
10:34AM 3 PROCESS OF THE MANUAL DOCUMENT COLLECTION SO THAT THEY'RE DONE  
10:34AM 4 IN ACCORDANCE WITH THE PROTOCOL.

10:34AM 5 I CAN TELL YOU THAT THIS IS SOMETHING THAT THE AGENCY HAS  
10:35AM 6 NEVER DONE BEFORE, AND FOR MANY DECADES THE WAY THAT WE  
10:35AM 7 RESPONDED TO SUBPOENAS AND OVERSIGHT REQUESTS AND FOIA AND  
10:35AM 8 DISCOVERY LITIGATION WAS THROUGH MANUAL COLLECTION, AND THIS IS  
10:35AM 9 AN EXTRA LAYER OF ASSURANCE THAT WE'LL PROVIDE THE PROCESS BY  
10:35AM 10 HAVING THAT TEAM HAND HOLD THE CUSTODIANS.

10:35AM 11 AND AS THE GOVERNMENT'S COUNSEL SAID, TEN OF THOSE  
10:35AM 12 CUSTODIANS ARE ATTORNEYS IN THE OFFICE OF CHIEF COUNSEL WHO  
10:35AM 13 ARE, YOU KNOW, BARRED AND PRACTICING ATTORNEYS.

10:35AM 14 I CAN SURELY TELL YOU THEY CAN BE TRUSTED TO DO IT  
10:35AM 15 ACCURATELY AND CORRECTLY.

10:35AM 16 SO THE THIRD CHALLENGE THAT WE HAVE HAD ARE WITH ARCHIVED  
10:35AM 17 DOCUMENTS, AND THOSE ARE FROM FORMER EMPLOYEES. THEY POSE  
10:35AM 18 SIGNIFICANT TECHNICAL CHALLENGES FOR US. THE FILES ARE  
10:35AM 19 COMPRESSED TO SAVE STORAGE, SO THEY HAVE TO BE DECOMPRESSED TO  
10:35AM 20 BE READABLE, AND THAT HAS BEEN A RESOURCE INTENSIVE PROCESS.

10:35AM 21 AND ALSO THE WAY THE FILES ARE ARCHIVED, THEY LOSE THEIR  
10:36AM 22 ATTACHMENTS IN THE ARCHIVING PROCESS SO THEY HAVE TO GO THROUGH  
10:36AM 23 A PROCESS THAT IS CALLED REHYDRATION TO ENSURE THAT THE E-MAILS  
10:36AM 24 ARE MATCHED WITH THEIR ATTACHMENT.

10:36AM 25 THE FDA IS USING A SOFTWARE CALLED SOURCE ONE FOR THIS



10:36AM 1 PROCESS. WE HAVE FOUND THAT THE SOURCE ONE SOFTWARE MAKES A  
10:36AM 2 BIG DIFFERENCE HOW MUCH EXPERIENCE PEOPLE HAVE WITH THE  
10:36AM 3 SOFTWARE AND HOW QUICKLY THEY CAN USE IT, AND THAT EXPERIENCE  
10:36AM 4 IS SOMETHING THAT CAN'T HAPPEN OVERNIGHT, BUT WE HAVE DIVERTED  
10:36AM 5 STAFF TO WORK WITH THE SOFTWARE AND TO GET TRAINED WHILE USING  
10:36AM 6 IT.

10:36AM 7 WE HAVE ALSO UPGRADED THE PROCESSING AND MEMORY ON THE  
10:36AM 8 SOURCE ONE SERVERS WHICH WAS EFFECTIVE AT THE END OF DECEMBER,  
10:36AM 9 AND LAST WEEK WE COMPLETED A STORAGE CAPACITY UPGRADE, AND  
10:36AM 10 WE'RE ALSO UPGRADING THE SOURCE ONE SOFTWARE THAT WILL BE  
10:36AM 11 COMPLETE BY THE END OF JANUARY.

10:36AM 12 AND I CAN TELL YOU THAT OUR I.T. STAFF IS VERY EXCITED  
10:36AM 13 ABOUT ALL OF THESE ENHANCEMENTS WE HAVE MADE AND UPGRADES THAT  
10:36AM 14 WE ARE MAKING, AND THEY BELIEVE IT WILL PROVIDE ADDITIONAL  
10:37AM 15 CAPACITY AND EFFICIENCY.

10:37AM 16 AGAIN, WITH THESE FILES, AS WITH THE OTHER FILES, WE'RE  
10:37AM 17 GOING TO GIVE THE DOJ THE NATIVE FILES, AND THEY'RE GOING TO  
10:37AM 18 RUN THE SEARCHS ON THEIR SOFTWARE.

10:37AM 19 SO WE ARE WORKING ON LONG-TERM IMPROVEMENTS THROUGH OUR  
10:37AM 20 DOCUMENT COLLECTION AND SEARCH CAPABILITIES, AND IT'S A HIGH  
10:37AM 21 AGENCY PRIORITY TO GET OUR E-DISCOVERY CAPABILITIES ON A STRONG  
10:37AM 22 FOOTING, AND THIS HAS GARNERED SIGNIFICANT AGENCY LEADERSHIP  
10:37AM 23 ATTENTION, BUT THERE ARE MANY LONG-TERM FIXES THAT REQUIRE A  
10:37AM 24 SIGNIFICANT INVESTMENT OF MONEY AND TALENT AND THEY CAN'T TAKE  
10:37AM 25 EFFECT ON THE TIMELINE THAT THE COURT HAS ORDERED. IT'S JUST

10:37AM 1 NOT TECHNICALLY POSSIBLE.

10:37AM 2 SO IN THE MEANTIME WE ARE BRINGING EVERY RESOURCE TO BEAR  
10:37AM 3 THAT WOULD BE HELPFUL TO THE PRODUCTION.

10:37AM 4 THE DOJ IS CUTTING DOWN ON A TREMENDOUS AMOUNT OF  
10:37AM 5 PRODUCTION TIME BY TAKING POSSESSION OF THE DOCUMENTS AND  
10:37AM 6 RUNNING THE SEARCHS, AND WE ARE NOT AWARE OF ANY OTHER  
10:37AM 7 RESOURCES THAT DOJ COULD OFFER AT THIS TIME OR THAT THE FDA  
10:37AM 8 COULD BRING TO BEAR THAT WOULD ALLOW US TO OVERCOME THE  
10:37AM 9 TECHNICAL LIMITATIONS THAT WE HAVE TO WORK WITHIN.

10:37AM 10 SO I APOLOGIZE TO THE COURT THAT I WAS NOT ABLE TO ATTEND  
10:38AM 11 THE HEARING IN PERSON, BUT WE DID SEND THREE ATTORNEYS FROM FDA  
10:38AM 12 TO BE THERE IN PERSON, INCLUDING OUR VERY EXPERIENCED ATTORNEY  
10:38AM 13 WE HIRED FROM ONE OF THE BIG D.C. LAW FIRMS TO OVERSEE OUR  
10:38AM 14 E-DISCOVERY WORK, AND THEY COULD ANSWER ANY QUESTIONS THAT THE  
10:38AM 15 COURT HAS OR I WOULD BE HAPPY TO.

10:38AM 16 AND I DO APPRECIATE THE OPPORTUNITY TO ADDRESS YOU.

10:38AM 17 THE COURT: WELL, THANK YOU, MS. AMIN. I APPRECIATE  
10:38AM 18 YOU JOINING THE CONVERSATION. I KNOW YOU HAVE A BUSY SCHEDULE.  
10:38AM 19 THIS IS AN IMPORTANT MATTER, AND I'M GRATEFUL FOR THE ATTENTION  
10:38AM 20 THAT YOU'VE PLACED TO THIS.

10:38AM 21 I WAS GOING TO ASK YOU WHETHER OR NOT -- WE HEARD  
10:38AM 22 MR. LEACH SAY THAT JUSTICE IS READY AND ABLE TO PROVIDE BODIES  
10:38AM 23 AND ABLE ASSISTANCE, BUT WHAT I HEARD YOU SAY IS -- I THINK I  
10:38AM 24 HEARD YOU SAY THAT ANYTHING THAT JUSTICE COULD DO AS FAR AS  
10:38AM 25 MORE BODIES IS NOT -- WOULD NOT BE HELPFUL.

10:38AM 1 MS. AMIN: AND THEY'RE PROVIDING BODIES ON THE  
10:39AM 2 SEARCHES, AND THAT HAS BEEN A HUGE HELP. I CAN -- OUR ORIGINAL  
10:39AM 3 ESTIMATES FOR HOW LONG IT WOULD TAKE TO COMPLY WITH THIS WERE A  
10:39AM 4 NUMBER OF MONTHS THAT YOU WON'T EVEN WANT TO HEAR US MENTION IN  
10:39AM 5 THIS COURT, BUT DOJ HAS PROVIDED THE RESOURCES TO RUN THE  
10:39AM 6 SEARCH WHICH HAS BROUGHT US TO THE POINT OF BEING ABLE TO  
10:39AM 7 COMMIT TO APRIL, AND THAT HAS BEEN A TREMENDOUS HELP.

10:39AM 8 BUT THERE ARE NOT ANY OTHER RESOURCES THAT THEY COULD  
10:39AM 9 OFFER THAT WOULD CHANGE THESE FUNDAMENTAL LIMITATIONS THAT WE  
10:39AM 10 HAVE.

10:39AM 11 THE COURT: IF YOU OBTAINED THE INFORMATION AND GAVE  
10:39AM 12 IT TO, AS THEY'RE DOING, I GUESS THE NATIVE DOCUMENTS TO  
10:39AM 13 JUSTICE NOW, AND THEY'RE DOING THE SEARCH WITH THEIR BODIES,  
10:39AM 14 THEIR TEAM, IS THAT SOMETHING THAT CAN BE ENHANCED, THAT IS,  
10:39AM 15 THE DELIVERY OF THE NATIVE DOCUMENTS, OR IS THAT TIED INTO THIS  
10:39AM 16 OTHER SOFTWARE ISSUE?

10:39AM 17 MS. AMIN: YEAH, IT'S THAT AND WE CONTINUE -- YOU  
10:39AM 18 KNOW, EVERY DAY WE'RE LOOKING FOR WAYS THAT WE CAN MAKE THAT  
10:39AM 19 DELIVERY OF THE NATIVE DOCUMENTS GO FASTER, BUT AS OF RIGHT NOW  
10:40AM 20 WE'RE NOT AWARE OF ANYTHING ELSE THAT WE COULD -- WE'VE TAKEN  
10:40AM 21 EVERY STEP THAT WE CAN IDENTIFY THAT WE CAN TAKE WITHIN THE  
10:40AM 22 TIME PERIOD THAT WE HAVE.

10:40AM 23 BUT WE CONTINUE TO HAVE LEADERSHIP CONVERSATIONS ABOUT  
10:40AM 24 THIS WITH OUR LEADERSHIP AND THE I.T. EXPERTS, AND CERTAINLY IF  
10:40AM 25 WE IDENTIFY ADDITIONAL WAYS THAT WE CAN MAKE THIS MOVE FASTER,

10:40AM 1 IF ANY OF IT WOULD INVOLVE ANY RESOURCES FROM DOJ, WE WOULD NOT  
10:40AM 2 HESITATE TO ASK.

10:40AM 3 THE COURT: OKAY. THANK YOU. I'M CURIOUS, HOW WAS  
10:40AM 4 THE APRIL 30TH DATE ARRIVED AT? HOW WAS THAT REACHED?

10:40AM 5 MS. AMIN: I CAN DEFER TO MY COLLEAGUES WHO ARE  
10:40AM 6 THERE IN THE COURTROOM IF THEY'RE ABLE TO WALK THROUGH STEP BY  
10:40AM 7 STEP, BUT IT'S JUST A MATTER OF 88 CUSTODIANS AND GAMING OUT  
10:40AM 8 HOW MUCH TIME THE SYSTEM IS TAKING TO ELECTRONICALLY DOWNLOAD  
10:40AM 9 COMBINED WITH HOW MUCH TIME WOULD IT TAKE TO VISIT TO MANUALLY  
10:40AM 10 COLLECT.

10:40AM 11 THE COURT: OKAY. WELL, MAYBE I'LL TURN TO --  
10:41AM 12 MR. WEINFELD, ARE YOU THE BEST TO ANSWER THAT QUESTION, SIR?

10:41AM 13 MR. WEINFELD: YES.

10:41AM 14 THE COURT: SURE, WHY DON'T YOU COME FORWARD. I'M  
10:41AM 15 CURIOUS, IS THERE AN APP? IS THERE AN ALGORITHM OR SOMETHING?  
10:41AM 16 HOW IS THAT REACHED?

10:41AM 17 MR. WEINFELD: THANK YOU, YOUR HONOR. THANK YOU,  
10:41AM 18 YOUR HONOR. THAT WAS BASED ON MY PROJECTION OF THE DOCUMENTS  
10:41AM 19 THAT WE HAD PRODUCED TO -- HAD TRANSMITTED TO DOJ TO DATE AT  
10:41AM 20 THE TIME I CAME UP WITH THE PROJECTION, PLUS THE INFORMATION  
10:41AM 21 THAT I WAS GIVEN FROM OUR I.T. STAFF ABOUT HOW LONG IT WOULD  
10:41AM 22 TAKE PER CUSTODIAN FOR EACH OF THE E-MAILS AND THE NETWORK  
10:41AM 23 DRIVES AND THE ARCHIVED CUSTODIANS.

10:41AM 24 THE COURT: SO HAS YOUR ESTIMATE CHANGED IN LIGHT OF  
10:41AM 25 WHAT WE LEARNED FROM MS. AMIN AND MR. LEACH ABOUT THE

10:41AM 1 PRODUCTION?

10:41AM 2 IT SOUNDS LIKE IT HAS BEEN ALL HANDS ON DECK AND THERE HAS  
10:41AM 3 BEEN SOME EFFICIENCIES THAT HAVE BEEN CAPTURED. HAS THAT  
10:41AM 4 CHANGED YOUR ESTIMATE?

10:41AM 5 MR. WEINFELD: I HAVEN'T CREATED A FORMAL ESTIMATE,  
10:41AM 6 YOUR HONOR, BUT I AM -- I WOULD BE DELIGHTED IF WE WERE ABLE TO  
10:41AM 7 PRODUCE ALL OF THE DOCUMENTS PRIOR TO APRIL 30TH.

10:42AM 8 I WOULDN'T GO SO FAR AS TO SAY THAT I'M HOPEFUL OF THAT,  
10:42AM 9 BUT I THINK THERE IS A POSSIBILITY OF THAT. I CERTAINLY WOULD  
10:42AM 10 NOT WANT TO COMMIT TO THAT AT THIS TIME.

10:42AM 11 IF IT PLEASE THE COURT, WE ARE ENGAGED IN QUITE A COMPLEX  
10:42AM 12 PROCESS. WE'VE DESCRIBED IT AS BUILDING A BOAT WHILE YOU'RE IN  
10:42AM 13 THE WATER.

10:42AM 14 SO EVERY DAY WE'RE TRYING TO FIND NEW EFFICIENCIES AND SO  
10:42AM 15 IT WOULD BE IMPRUDENT TO COME UP WITH A SPECIFIC ESTIMATE NOW.

10:42AM 16 NOW, IF THE COURT WISHES ONE, I'D BE HAPPY TO GET BACK IN  
10:42AM 17 TOUCH WITH MY COLLEAGUES AND COME UP WITH ONE.

10:42AM 18 THE COURT: I WAS CURIOUS, THIS DATE WAS SELECTED  
10:42AM 19 AND I'VE HEARD THE REASONS PERHAPS NOW.

10:42AM 20 MR. WEINFELD: DRILLING DOWN JUST A LITTLE BIT, IT  
10:42AM 21 HAD TO DO WITH HOW MANY CUSTODIANS WE COULD COLLECT  
10:42AM 22 CONCURRENTLY, HOW LONG IT MIGHT TAKE TO PROCESS THAT DATA, HOW  
10:42AM 23 LONG IT WOULD TAKE TO, AS MS. AMIN COMMENTED EARLIER, REHYDRATE  
10:42AM 24 THE CUSTODIANS. THAT'S A PARTICULARLY DIFFICULT PROCESS THAT  
10:42AM 25 REQUIRES SOMEONE WITH EXPERTISE AND EXPERIENCE IN THAT AREA.

10:42AM 1 SO I PUT THOSE NUMBERS TOGETHER AND CAME UP WITH THAT  
10:43AM 2 BASED ON A VERY GRANULAR ANALYSIS.

10:43AM 3 THE PLACES WHERE WE MIGHT GAIN SPEED MIGHT BE IN THE  
10:43AM 4 E-MAIL COLLECTION, PERHAPS A BIT OF SPEED ON THE NETWORK  
10:43AM 5 COLLECTION.

10:43AM 6 BUT BEING PRUDENT, APRIL 30TH IS A DEADLINE THAT WE CAN  
10:43AM 7 CERTAINLY MEET.

10:43AM 8 THE COURT: GREAT. THANK YOU VERY MUCH. THANK YOU  
10:43AM 9 FOR BEING HERE.

10:43AM 10 MR. WEINFELD: YOU'RE VERY WELCOME.

10:43AM 11 MR. LEACH, ANYTHING ELSE YOU WOULD LIKE TO ADD?

10:43AM 12 MR. LEACH: NO, YOUR HONOR. THANK YOU VERY MUCH.

10:43AM 13 THE COURT: ALL RIGHT. THANK YOU. WHO IS GOING TO  
10:43AM 14 SPEAK FOR THE DEFENSE?

10:43AM 15 MR. WADE: LANCE WADE ON BEHALF OF THE DEFENSE.

10:43AM 16 HAPPY NEW YEAR. IT'S NICE TO BE BACK IN CALIFORNIA.

10:43AM 17 THE COURT: THANKS. HAPPY NEW YEAR.

10:43AM 18 MR. WADE: THE -- WE DON'T WANT TO -- WE HEAR  
10:43AM 19 EVERYTHING THAT'S BEEN SAID HERE, AND WE DON'T WANT TO APPEAR  
10:43AM 20 UNREASONABLE OR UNAPPRECIATIVE.

10:43AM 21 THE COURT: BUT.

10:43AM 22 MR. WADE: THERE'S A TREMENDOUS AMOUNT OF WORK. THE  
10:43AM 23 BUT WILL COME IN A SECOND. THERE'S A TREMENDOUS AMOUNT OF WORK  
10:44AM 24 BEING DONE, AND I DON'T WANT TO BE DISRESPECTFUL OF THAT GIVEN  
10:44AM 25 THE HARD WORK THAT IS BEING PUT IN BY PEOPLE -- THE OPPOSING

10:44AM 1 COUNSEL AND PEOPLE WITH THE GOVERNMENT.

10:44AM 2 THE COURT: IT SEEMS LIKE IT'S A SIGNIFICANT EFFORT  
10:44AM 3 THAT HAS BEEN CALLED UPON, AND WHAT WE'VE HEARD TODAY AND IN  
10:44AM 4 THE DECLARATIONS SUGGESTS THAT THEY'VE RISEN TO THE CHALLENGE  
10:44AM 5 AS BEST THEY CAN WITH THE TOOLS THAT THEY HAVE AVAILABLE.

10:44AM 6 MR. WADE: IT WOULD SEEM LIKE THERE IS SOME  
10:44AM 7 BOTTLENECKS IN THE PROCESS BASED ON THE TECHNOLOGY THAT THEY  
10:44AM 8 EMPLOY AT THE AGENCY THAT ARE LIMITING THE CAPACITY HERE AND  
10:44AM 9 WITHOUT -- I DON'T HAVE THE TECHNICAL CAPACITY TO TELL THE  
10:44AM 10 COURT THAT THERE IS SOME ALTERNATIVE TO FIX THAT BOTTLENECK.  
10:44AM 11 IT'S POSSIBLE THAT SOME OUTSIDE VENDOR CAN BE BROUGHT IN, BUT  
10:44AM 12 IT SOUNDS LIKE THEY'RE MAKING GREAT EFFORTS TO TRY TO DO THAT  
10:44AM 13 AND TO DEVELOP WHATEVER RESOURCES THEY CAN BRING TO THIS  
10:44AM 14 MATTER. WE'RE APPRECIATIVE OF THAT.

10:44AM 15 OUR POSITION ON THIS MOTION IS NOT GUIDED BY OUR LACK OF  
10:45AM 16 APPRECIATION OF THOSE EFFORTS.

10:45AM 17 IT'S JUST GUIDED BY A PRACTICAL REALITY OF THE CALENDAR,  
10:45AM 18 WHICH IS THE VOLUME OF DOCUMENTS HERE, AND THERE'S A LOT OF  
10:45AM 19 DISCUSSION THAT HAS BEEN -- THAT HAS OCCURRED WITH RESPECT TO  
10:45AM 20 THE SEARCH TERMS AND THE NUMBER OF CUSTODIANS.

10:45AM 21 THE PROOF IS IN THE PUDDING HERE, YOUR HONOR. ONE HUNDRED  
10:45AM 22 AND FORTY THOUSAND DOCUMENTS HAVE COME TO THE DEFENSE THAT ARE  
10:45AM 23 RESPONSIVE TO THOSE SIX CATEGORIES OF DOCUMENTS.

10:45AM 24 I REVIEWED A STACK OF THEM ON THE PLANE RIDE OUT HERE, THE  
10:45AM 25 MORE RECENT MATERIALS. THESE ARE DOCUMENTS THAT ARE MATERIAL

1 TO THE PREPARATION OF THE DEFENSE AND SIGNIFICANT DOCUMENTS.

2 SO WE NEED THE MATERIAL. WE NEED TIME TO DIGEST THE  
3 MATERIAL, AND WE CAN'T DO THAT AND BE READY TO MEET THE VARIOUS  
4 DEADLINES THAT HAVE BEEN IMPOSED BY THE COURT OR THAT WE HAVE  
5 PREVIOUSLY AGREED TO WITH THE ASSUMPTION THAT WE WOULD HAVE  
6 THIS MATERIAL EARLIER.

7 THE COURT: WELL, DID YOU RECEIVE 136,092 DOCUMENTS  
8 BY DECEMBER 31ST?

9 MR. WADE: WE DID. I USED THE NUMBER OF ABOUT  
10 140,000 BECAUSE I THINK THERE IS ANOTHER SMALL PRODUCTION THAT  
11 WAS MADE BEFORE THEN. THE PRECISE NUMBER MIGHT BE --

12 THE COURT: RIGHT. RIGHT. HAVE YOU COMPLETED YOUR  
13 WORK?

14 MR. WADE: NO.

15 THE COURT: RIGHT.

16 MR. WADE: AND TO THAT POINT, YOUR HONOR, WHICH IS  
17 EXACTLY WHY WE TAKE THE POSITION THAT WE'RE TAKING BEFORE THE  
18 COURT, I DID SOME MATH ON THIS LAST NIGHT AS I WAS GOING  
19 THROUGH IT, AND USING, USING THE AVERAGE RETURN, AVERAGE REVIEW  
20 RATES FOR DOCUMENTS OF THIS TYPE AND BASED ON THE REVIEW RATE  
21 OF THE PREVIOUS DOCUMENTS THAT WE'VE RECEIVED, IT WOULD TAKE A  
22 REVIEW TEAM TEN -- OF TEN PEOPLE, ABOUT THREE MONTHS JUST TO  
23 GET THROUGH JUST THE FIRST TRANCHE OF DOCUMENTS WITH A  
24 COMPREHENSIVE FIRST LEVEL REVIEW.

25 THAT'S TO SAY NOTHING OF THE FOLLOW-ON ANALYSIS THAT IS



10:46AM 1 DONE BY ASSOCIATES AND PARTNERS TO INTEGRATE THAT INTO OUR  
10:46AM 2 EXPERT WORK, TO INTEGRATE THAT INTO THE WORK THAT WE'RE DOING  
10:47AM 3 TO BE PREPARED TO EXAMINE WITNESSES, THE INVESTIGATIVE WORK  
10:47AM 4 THAT WE WANT TO DO TO DETERMINE WHETHER WE CALL ADDITIONAL  
10:47AM 5 WITNESSES.

10:47AM 6 SO WE'RE, WE'RE -- LIKE THE GOVERNMENT AND THE FDA, WE'RE  
10:47AM 7 PREPARED TO WORK VERY HARD ON THIS, BUT THERE'S JUST A  
10:47AM 8 PRACTICAL REALITY BASED UPON THE VOLUME HERE TO BE IN A  
10:47AM 9 POSITION WHERE WE CAN PROPERLY DEFEND OUR CLIENT, WE CAN'T  
10:47AM 10 AGREE TO THIS DEADLINE.

10:47AM 11 OF COURSE, WE WISH THESE RESOURCES HAD BEEN DEDICATED  
10:47AM 12 SOONER. WE WISHED THAT THIS HAPPENED BACK IN -- WHEN WE FILED  
10:47AM 13 THE MOTION IN APRIL OR AT THE PRIOR HEARINGS.

10:47AM 14 THE COURT: WELL, MS. AMIN TELLS US THIS IS A CASE  
10:47AM 15 OF FIRST IMPRESSION TO HER AGENCY, THE SIZE OF THE REQUEST.

10:47AM 16 MR. WADE: I CERTAINLY CAN'T SPEAK TO THE FDA'S  
10:47AM 17 EXPERIENCE ON THESE MATTERS. I CAN REPRESENT TO THE COURT, AS  
10:47AM 18 WE HAVE MENTIONED BEFORE, WE HAVE DONE A LOT OF CRIMINAL  
10:47AM 19 LITIGATION INVOLVING VARIOUS GOVERNMENT AGENCIES, GIVEN OUR  
10:48AM 20 PRACTICE AND THE LOCATION OF OUR PRACTICE, AND RECEIVING A  
10:48AM 21 VOLUME OF THIS SIZE FROM A GOVERNMENT AGENCY IN CONNECTION WITH  
10:48AM 22 A CRIMINAL CASE IS NOT UNPRECEDENTED IN OUR EXPERIENCE.

10:48AM 23 NOW --

10:48AM 24 THE COURT: WITH THE FDA IN YOUR EXPERIENCE?

10:48AM 25 MR. WADE: NOT WITH -- I HAVE NOT HAD THAT WITH THE

FDA BUT OTHER AGENCIES WE HAVE SEEN SIMILAR VOLUME.

NOW, TO BE CLEAR, A LOT OF TIMES THOSE MATERIALS ARE GATHERED AS PART OF THE INVESTIGATION, AND A BROADER SET OF RELEVANT MATERIALS IS GATHERED DURING THE INVESTIGATION STAGE AND TURNED OVER.

IT WAS CLEAR TO US AT THE OUTSET THAT THE UNIVERSE OF MATERIAL THAT WAS GATHERED HERE WAS VERY NARROW AND TO A DEGREE CURATED TO THE GOVERNMENT'S CASE, THE CASE THAT IT WANTED TO PRESENT, WHICH IS FINE. THE GOVERNMENT HAS ITS JOB. WE HAVE OURS.

OUR JOB IS TO DEFEND OUR CLIENT, AND, THEREFORE, ADDITIONAL MATERIALS ARE RELEVANT TO THOSE EFFORTS.

I MIGHT BE IN A DIFFERENT POSITION IF THESE ROLLING PRODUCTIONS THAT HAD OCCURRED TO DATE WERE NOT YIELDING RESULTS THAT WE WOULD REPRESENT TO THE COURT TO BE HIGHLY SIGNIFICANT DOCUMENTS, EXHIBIT LIST TYPE DOCUMENTS. AND WE HAVE EVERY REASON TO ANTICIPATE THAT THAT WILL CONTINUE.

NOW, THAT BEING SAID, WE'VE, WE'VE -- WE'RE LEARNING NEW INFORMATION, SOME OF THE INFORMATION THAT HAS BEEN SHARED BY FDA COUNSEL AND HAS BEEN SHARED BY THE GOVERNMENT TODAY WE'RE ACTUALLY LEARNING FOR THE FIRST TIME IN THE COURTROOM WITH RESPECT TO SOME OF THE ISSUES, AND THE TYPE OF PROPOSAL THAT THEY'RE MAKING WITH RESPECT TO SOME OF THOSE CUSTODIANS WHO ARE LOWER PRIORITY CUSTODIANS, MANY OF WHOM ARE LAWYERS, AND I'M CONFIDENT THAT IN AN EFFORT TO TRY TO EXPEDITE THIS WE PROBABLY

10:49AM 1 COULD COME UP WITH A PROCESS THAT WOULD ALLOW FOR A MANUAL  
10:49AM 2 SEARCH WITH THE TYPES OF PROCEDURES THAT MS. AMIN WAS REFERRING  
10:49AM 3 TO WITH SOME FDA ATTORNEY SUPERVISION, DOJ ATTORNEY  
10:50AM 4 SUPERVISION, MAYBE A CERTIFICATION FROM THE PERSON THAT THEY  
10:50AM 5 DID WHAT THEY SAID THEY COULD DO. I THINK WE CAN COME UP WITH  
10:50AM 6 A PROTOCOL TO HELP EXPEDITE IT.

10:50AM 7 BUT MY UNDERSTANDING OF WHAT THE GOVERNMENT'S POSITION IS,  
10:50AM 8 EVEN WITH THAT EFFICIENCY, WE'RE STILL LOOKING AT THE END OF  
10:50AM 9 APRIL, WHICH IS A DEADLINE THAT I THINK, AS THE COURT KNOWS,  
10:50AM 10 INCLUDES -- THE VERY DATE IS THE DATE ON WHICH OUR EXPERT  
10:50AM 11 DISCLOSURES ARE DUE, IT'S JUST A DAY BEFORE OUR RULE 16  
10:50AM 12 DISCOVERY IS DUE. IT'S JUST --

10:50AM 13 THE COURT: WELL, WE CAN MAKE SOME ADJUSTMENT, OF  
10:50AM 14 COURSE, AS NEEDED ON THINGS. COURTS DO THAT.

10:50AM 15 BUT I APPRECIATE YOUR ATTENTION TO RESPECTING THE  
10:50AM 16 DEADLINES.

10:50AM 17 MR. WADE: AND WE HAVE MADE EVERY EFFORT TO TRY TO  
10:50AM 18 PUSH TOWARDS THAT.

10:50AM 19 YOUR HONOR MAY RECALL THAT AS FAR BACK AS JUNE AND JULY  
10:50AM 20 WHEN WE WERE IN OUR FIRST AND SECOND HEARING ON THESE MATTERS  
10:51AM 21 AND WERE AT THE SAME TIME TALKING ABOUT THE TRIAL, WE  
10:51AM 22 ARTICULATED, BECAUSE THE COURT ADVANCED THE TRIAL DATE SLIGHTLY  
10:51AM 23 OVER WHAT THE PARTIES HAD OFFERED TO THE COURT, WE TRIED TO  
10:51AM 24 MAKE CLEAR TO THE COURT THAT WE SAW LITTLE ROOM FOR ERROR IN  
10:51AM 25 CONNECTION WITH SOME OF THESE DISCOVERY ISSUES GIVEN HOW TIGHT

10:51AM 1 THIS IS.

10:51AM 2 THIS IS A -- THIS CASE AND IN THE PROCESS THE FDA IS GOING  
10:51AM 3 THROUGH IS IN SOME WAYS A MICROCOSM OF THE WHOLE CASE. IT'S A  
10:51AM 4 HIGHLY COMPLEX CASE, AND IT'S GOING TO BE A LENGTHY TRIAL AND  
10:51AM 5 IT INVOLVES A LOT OF WITNESSES. THERE IS ONLY SO MUCH WE CAN  
10:51AM 6 DO AND BE IN A POSITION TO FULLY AND FAIRLY REPRESENT OUR  
10:51AM 7 CLIENT BEFORE THE COURT AT TRIAL AND EFFICIENTLY BEFORE THE  
10:51AM 8 COURT. WE DON'T WANT TO -- WE WANT TO DO IT IN A WAY THAT IS  
10:51AM 9 RESPECTFUL OF THE COURT OBVIOUSLY IN ITS TIME AS WELL.

10:51AM 10 SO THAT IS THE GENESIS OF OUR OPPOSITION.

10:51AM 11 THE COURT: WELL, I APPRECIATE IT. I'VE OFTEN  
10:52AM 12 COMMENTED IT'S -- I'VE DONE THIS, I'VE USED THE WORD  
10:52AM 13 "EFFICIENT" WITH A CRIMINAL CASE, AND IT'S PROBABLY NOT  
10:52AM 14 APPROPRIATE TO DO THAT, RESPECTING ALL PARTIES' INTERESTS IN  
10:52AM 15 THE CASE. EFFICIENCY IS IMPORTANT, BUT RESPECTING BOTH  
10:52AM 16 PARTIES' RIGHTS TO A FAIR TRIAL IS PARAMOUNT, SO I APPRECIATE  
10:52AM 17 THAT.

10:52AM 18 MR. WADE: YOUR HONOR, TO BE CLEAR, I THINK THAT ALL  
10:52AM 19 PARTIES HERE, ESPECIALLY AFTER THE NOVEMBER ORDER, PARTICULARLY  
10:52AM 20 AFTER THE NOVEMBER ORDER, HAVE BEEN WORKING DILIGENTLY TO TRY  
10:52AM 21 TO BE, IF NOT EFFICIENT, EXPEDITIOUS TO HELP GET -- KEEP THIS  
10:52AM 22 CASE ON TRACK, AND I'M NOT BELITTLING THOSE EFFORTS, I'M JUST  
10:52AM 23 REFLECTING THE REALITY.

10:52AM 24 WE NEED TO BE -- AS YOUR HONOR KNOWS, WE NEED TO BE  
10:52AM 25 THOROUGH AND ZEALOUS, I BELIEVE, IN OUR REPRESENTATION OF OUR

1 CLIENT, AND TO DO THAT WE WOULD NOT BE ABLE TO DO THAT ON THE  
2 SCHEDULE.

3 THE COURT: OKAY. ALL RIGHT. THANK YOU.

4 MR. BROWN, MR. CAZARES.

5 MR. CAZARES: THANK YOU. THANK YOU.

6 STEPHEN CAZARES FOR MR. BALWANI. I WON'T REITERATE WHAT  
7 COUNSEL HAS ALREADY MENTIONED WITH RESPECT TO THE NEED FOR  
8 THESE IMPORTANT MATERIALS. I THINK THAT HAS ALREADY BEEN MADE  
9 CLEAR.

10 BUT THE CIRCUMSTANCE THAT WE'RE NOW IN FROM THE DEFENSE  
11 PERSPECTIVE, OUT OF KIND OF NO FAULT OF OUR OWN, YOU KNOW, THE  
12 GOVERNMENT CHOSE TO BRING THIS CASE 19 MONTHS AGO NOW.

13 THE COURT: WELL, I WOULD -- I'M MORE INTERESTED IN  
14 NOT CASTING BLAME BUT FINDING SOLUTIONS.

15 MR. CAZARES: AND I'M NOT CASTING BLAME. MY POINT,  
16 THOUGH, IS THAT WE'RE NOW AT THIS STAGE WITH TRIAL APPROACHING  
17 AND VOLUMINOUS MATERIALS ARE NOW BEING PRODUCED TO THE DEFENSE,  
18 WHICH WE REALLY APPRECIATE. AND AS COUNSEL MENTIONED, YOU  
19 KNOW, WE'RE PUT IN THIS TIME PRESSURE WHERE WE NEED TO REVIEW  
20 THESE MATERIALS TO PREPARE FOR TRIAL, BUT THERE'S THE  
21 COUNTERVAILING INTEREST, WE WANT TO GET THIS CASE DONE. WE  
22 WOULD LIKE TO GO TO TRIAL. MR. BALWANI WOULD LIKE TO CLEAR HIS  
23 NAME. THAT'S THE SPEEDY TRIAL ACT ISSUE.

24 THE PROBLEM NOW IS THAT WE'RE BEING PUT IN THE SITUATION  
25 THROUGH -- OUT OF NO INTENT I DON'T BELIEVE BY THE GOVERNMENT,

10:54AM 1 WE'RE BEING PUT IN THE POSITION OF KIND OF WEIGHING OUR NEED TO  
10:54AM 2 PREPARE FOR TRIAL VERSUS OUR DESIRE TO GET TO TRIAL AND TO TRY  
10:54AM 3 TO CLEAR MR. BALWANI'S NAME, AND THAT'S WHAT IS HAPPENING HERE  
10:54AM 4 IN THE COURT, AND THEN THERE ARE OTHER COUNTERVAILING ISSUES  
10:54AM 5 THAT WE ON THE DEFENSE HAVE TO CONSIDER AS WELL. THAT'S,  
10:54AM 6 UNFORTUNATELY, YOU KNOW, THE MEDIA COVERAGE OF THE CASE, PUBLIC  
10:54AM 7 PERCEPTIONS. THERE'S APPARENTLY A MOVIE THAT IS GOING TO BE  
10:54AM 8 COMING OUT SOME TIME ABOUT THESE EVENTS, WHICH I'M SURE AREN'T  
10:54AM 9 GOING TO CAST MY CLIENT IN A POSITIVE LIGHT AND MAY HAVE SOME  
10:54AM 10 IMPACT ON THE JURY POOL AS WELL.

10:54AM 11 AND THESE ARE -- I KNOW THE COURT CAN'T CONTROL THAT, BUT  
10:54AM 12 THESE ARE ALL THINGS THAT WE HAVE TO CONSIDER WHEN TRYING TO  
10:54AM 13 MAKE OUR DECISIONS GOING FORWARD WITH RESPECT TO, YOU KNOW,  
10:54AM 14 REVIEWING THIS DISCOVERY AND ULTIMATELY THE DIFFICULT CALENDAR  
10:54AM 15 WE'RE IN RIGHT NOW.

10:55AM 16 THE COURT: OKAY. THANK YOU.

10:55AM 17 MR. CAZARES: THANK YOU, YOUR HONOR.

10:55AM 18 THE COURT: THANK YOU FOR THOSE OBSERVATIONS.

10:55AM 19 MR. LEACH, ANYTHING FURTHER?

10:55AM 20 MR. LEACH: VERY BRIEFLY, YOUR HONOR. THIS IS -- I  
10:55AM 21 DON'T WANT TO LOSE SIGHT OF THE FACT THAT, FIRST OF ALL,  
10:55AM 22 MR. BALWANI IS NOT HERE BECAUSE HE'S DEPOSING TEN FDA WITNESSES  
10:55AM 23 BACK IN WASHINGTON, D.C. I THINK MR. BALWANI HAS A VERY GOOD  
10:55AM 24 UNDERSTANDING OF THE FDA ISSUES AND WAS PREPARED ENOUGH TO GO  
10:55AM 25 FORWARD WITH THOSE DEPOSITIONS IN THE CIVIL CASE, SO I DON'T

1 WANT TO LOSE SIGHT OF THE FACT THAT THIS IS ONE ISSUE IN THE  
2 INDICTMENT.

3 THERE ARE AT LEAST TEN OTHER CATEGORIES OF  
4 MISREPRESENTATIONS HERE. THIS IS NOT A CASE ABOUT THE FDA  
5 INVOLVING THE FDA CHARGES. I DON'T WANT TO MINIMIZE THE  
6 IMPORTANCE OF THESE DOCUMENTS, AND WE ARE RESPONDING TO THE SIX  
7 CATEGORIES IN THE MOTION TO COMPEL. I'M NOT TRYING TO MINIMIZE  
8 THEM. I'M JUST TRYING TO PUT THEM IN PERSPECTIVE OF A MUCH  
9 LARGER CASE. THIS IS NOT A CASE ABOUT THE FDA. THIS IS A CASE  
10 ABOUT MISREPRESENTATIONS TO INVESTORS AND REPRESENTATIONS --

11 THE COURT: IT'S A WIRE FRAUD CASE.

12 MR. LEACH: IT'S A WIRE FRAUD CASE AS I UNDERSTAND  
13 IT, TOO, YOUR HONOR.

14 SO I ALSO -- I TAKE THE DEFENSE AT THEIR WORD THAT THEY  
15 NEED THE TIME TO PREPARE. THEY'RE BEST ABLE TO SPEAK TO  
16 THOSE -- BETTER ABLE TO SPEAK TO THOSE THAN I AM.

17 I WOULD ENCOURAGE THE MORE SPECIFICS THAT WE CAN HAVE ON  
18 THAT. YOU KNOW, I KEEP HEARING REFERENCES TO HIGHLY RELEVANT  
19 EVIDENCE THAT THEY FOUND IN THE 130-PLUS THOUSAND DOCUMENTS,  
20 AND I'M NOT SURE WHAT THEY'RE REFERRING TO. I WOULD ENCOURAGE  
21 THE COURT TO LOOK AT THE SPECIFICITY OF THAT.

22 AND WE WANT TO KEEP THIS TRIAL DATE. WE'RE WORKING TO  
23 KEEP THIS TRIAL DATE.

24 THE DEFENSE, YOU KNOW, WE TAKE THEM AT THEIR WORD FOR WHAT  
25 THEY NEED, AND WE'RE WORKING AS QUICKLY AS WE CAN TO GET IT TO

10:57AM 1 THEM.

10:57AM 2 THANK YOU, YOUR HONOR.

10:57AM 3 THE COURT: ALL RIGHT. I THINK OUR NEXT COURT DATE

10:57AM 4 IS FEBRUARY 10TH.

10:57AM 5 MR. LEACH: YES, YOUR HONOR.

10:57AM 6 THE COURT: THAT IS FOR MOTIONS.

10:57AM 7 LET ME INVITE COUNSEL TO SIDE-BAR, AND IF YOU COULD BRING

10:57AM 8 YOUR CALENDARS, PLEASE. I JUST WANT TO GO OVER SOME SCHEDULING

10:57AM 9 QUESTIONS.

10:57AM 10 **(SIDE-BAR CONFERENCE ON A SEALED RECORD PAGES 41-44)**

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25



10:57AM 1 (SEALED SIDE-BAR CONFERENCE.)

10:57AM 2 THE COURT: ARE WE ALL GOING TO FIT? WE'RE AT  
10:57AM 3 SIDE-BAR WITH COUNSEL. I JUST WANT TO TALK ABOUT SOME  
10:57AM 4 SCHEDULING MATTERS WITH YOUR CALENDARS, AND YOU'RE ALL GOING TO  
10:57AM 5 LOOK AT YOUR CALENDARS NOW SO EVERYBODY OUT IN THE AUDIENCE CAN  
10:57AM 6 SEE YOU SEARCHING YOUR CALENDARS.

10:57AM 7 WHAT I HAVE SOME QUESTIONS ABOUT, THERE ARE SO MANY SEALED  
10:57AM 8 DOCUMENTS IN THIS CASE, AND WE'RE HAVING SOME DIFFICULTY  
10:57AM 9 TRACKING THOSE. I SAID "DIFFICULTY." WE'VE PUT TOGETHER A  
10:57AM 10 LIST THAT I WANT TO SHARE WITH ALL OF YOU TO MAKE SURE THAT YOU  
10:57AM 11 HAVE WHAT WE HAVE, AND I'VE ASKED OUR STAFF TO DO THAT, AND  
10:58AM 12 THEY'VE PUT THAT TOGETHER.

10:58AM 13 I WANT TO GIVE YOU THAT.

10:58AM 14 MS. KRATZMANN WILL GIVE YOU THAT AT THE CLOSE WHEN WE  
10:58AM 15 LEAVE TODAY. I'M NOT GOING TO HAND YOU ANYTHING FROM THE BENCH  
10:58AM 16 HERE.

10:58AM 17 WHAT I WANT TO DO IS TO TALK ABOUT A SCHEDULING FOR THIS  
10:58AM 18 12.2(B). ONE OF THE ISSUES THAT COMES UP IS BECAUSE EVERYTHING  
10:58AM 19 IS UNDER SEAL, I CAN'T HAVE THAT INFORMATION ON THE RECORD  
10:58AM 20 HERE.

10:58AM 21 WHAT I WANT TO PROPOSE TO YOU IS THAT I'M GOING TO LEAVE  
10:58AM 22 THE FEBRUARY 10TH DATE, I'M NOT GOING TO DISTURB THAT. I'M  
10:58AM 23 GOING TO ANNOUNCE THAT WHEN I GO BACK.

10:58AM 24 BUT I'M GOING TO INVITE YOU TO COME BACK EITHER AT 1:00  
10:58AM 25 O'CLOCK OR 2:30 TODAY, AND WE'LL HAVE A SEALED DISCUSSION ABOUT

10:58AM 1 SCHEDULING AND SOME OTHER ISSUES IF THAT -- DOES THAT WORK FOR  
10:58AM 2 YOU, MR. SCHENK?

10:58AM 3 MR. SCHENK: YOUR HONOR, IT WORKS FINE FOR OUR  
10:58AM 4 SCHEDULE. I'M CONCERNED THAT ONE OF THE ISSUES IS SEVERANCE,  
10:58AM 5 AND MR. BALWANI IS NOT PRESENT.

10:58AM 6 THE COURT: RIGHT. AND THAT PRESENTS A PROBLEM TO  
10:59AM 7 ME, AND I WAS TOLD THAT THERE WAS AN E-MAIL THAT SUGGESTED HE  
10:59AM 8 WOULDN'T BE PRESENT, AND I DO WANT TO TALK ABOUT THAT. THAT'S  
10:59AM 9 ONE OF THE THINGS THAT I DO WANT TO TALK ABOUT.

10:59AM 10 MR. CAZARES: STEPHEN CAZARES FOR MR. BALWANI. TO  
10:59AM 11 THE EXTENT THAT THE DISCUSSION IS ABOUT THE CALENDARING ISSUE  
10:59AM 12 OR THE DATES, I THINK WE CAN ADDRESS THAT. TO THE EXTENT THAT  
10:59AM 13 SOME FINAL DECISIONS NEED TO BE MADE, WE NEED TO SPEAK WITH  
10:59AM 14 MR. BALWANI.

10:59AM 15 THE COURT: WELL, PART OF MY CONVERSATION IS GOING  
10:59AM 16 TO BE -- CANDIDLY, I HAVE SOME QUESTIONS ABOUT THE STATUS OF  
10:59AM 17 THAT MOTION, YOUR SEVERANCE, YOUR SEVERANCE, AND ALSO ABOUT  
10:59AM 18 MS. HOLMES AND THAT THE NOTICE OF 12.2(B), WHAT DOES THAT  
10:59AM 19 REALLY MEAN?

10:59AM 20 SO THOSE ARE THINGS THAT WE WILL TALK ABOUT THIS  
10:59AM 21 AFTERNOON.

10:59AM 22 MR. CAZARES: MAY I SUGGEST, I DON'T THINK THERE ARE  
10:59AM 23 ANY DEPOSITIONS TODAY. CAN MR. BALWANI CALL IN TO THE HEARING?

10:59AM 24 THE COURT: MR. CAZARES WILL CHECK IN AND LET US  
11:00AM 25 KNOW.

11:00AM 1 MR. CAZARES: HE MAY BE ABLE TO.

11:00AM 2 THE COURT: LET ME -- I HAVE A 1:30 CRIMINAL  
11:00AM 3 CALENDAR. SO IF WE MEET AT 1:00 O'CLOCK, I THINK WE'RE GOING  
11:00AM 4 TO BE COMPRESSED INTO THAT. MY SUGGESTION IS THAT THE 2:30  
11:00AM 5 WOULD PROBABLY GIVE US THE BALANCE OF THE AFTERNOON. IF YOU  
11:00AM 6 CAN DELAY YOUR FLIGHTS FOR THAT LONG.

11:00AM 7 THEN WHAT WE'LL DO IS WE'LL COME BACK -- AS I SAID, I'M  
11:00AM 8 GOING TO SEAL THE TRANSCRIPT OF THIS CONVERSATION AS WELL, AND  
11:00AM 9 THEN WE CAN FINISH THE CONVERSATION ABOUT WHAT TO DO ABOUT  
11:00AM 10 THESE OTHER ISSUES BECAUSE I DO HAVE SOME QUESTIONS ABOUT IT.

11:00AM 11 AND WE NEED TO ALSO DECIDE ABOUT WHEN DO WE, WHEN DO WE  
11:00AM 12 STOP SEALING DOCUMENTS, AND WHAT DO WE ACTUALLY HAVE PUBLIC  
11:00AM 13 CONVERSATIONS ABOUT THINGS?

11:00AM 14 AND I'VE SEALED THINGS NOW BECAUSE OF OBVIOUSLY -- I'VE  
11:00AM 15 LOOKED AT YOUR DECLARATIONS, AND I CAPTURE THAT. IT'S  
11:00AM 16 NECESSARY TO DO IT.

11:00AM 17 AT SOME POINT WE'RE GOING TO HAVE TO GO ON THE RECORD  
11:01AM 18 ABOUT THIS. SO THOSE ARE THINGS THAT WE'LL TALK ABOUT THIS  
11:01AM 19 AFTERNOON.

11:01AM 20 SHOULD WE SAY 2:30 THEN?

11:01AM 21 MR. CAZARES: THAT'S FINE, YOUR HONOR.

11:01AM 22 MR. SCHENK: YES.

11:01AM 23 THE COURT: SO WHAT I'M GOING TO DO THEN, IS I'M NOT  
11:01AM 24 GOING TO DISTURB OUR FEBRUARY 10TH DATE. THAT'S GOING TO BE  
11:01AM 25 THE NEXT COURT DATE THAT I ANNOUNCE, AND THEN I'LL SEE YOU BACK

11:01AM 1

HERE AT 2:30.

11:01AM 2

MR. CAZARES: THANK YOU, YOUR HONOR.

11:01AM 3

MR. WADE: THANK YOU, YOUR HONOR.

11:01AM 4

MR. LEACH: THANK YOU VERY MUCH.

11:01AM 5

**(END OF SEALED DISCUSSION AT SIDE-BAR.)**

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

11:01AM 1 (IN OPEN COURT.)

11:01AM 2 THE COURT: ALL RIGHT. THANK YOU, COUNSEL. THEN  
11:01AM 3 THE COURT IS NOT GOING TO DISTURB THE FEBRUARY 10TH DATE. I  
11:01AM 4 THINK THAT'S BEEN SET, AND THAT WILL REMAIN AS SET FOR FURTHER  
11:01AM 5 HEARING.

11:01AM 6 I'M NOT GOING TO DECIDE THE GOVERNMENT'S MOTION NOW. I'M  
11:01AM 7 GOING TO TAKE THAT MATTER UNDER SUBMISSION. I MAY HAVE MORE  
11:01AM 8 QUESTIONS, AND I MAY ASK THE PARTIES FOR ADDITIONAL INFORMATION  
11:01AM 9 ABOUT THIS.

11:01AM 10 MS. AMIN, MR. GORGI, I APPRECIATE YOUR APPEARANCE  
11:01AM 11 TELEPHONICALLY.

11:02AM 12 IS THERE ANYTHING ELSE YOU WOULD LIKE TO ADD BEFORE WE END  
11:02AM 13 THIS MORNING'S SESSION?

11:02AM 14 MS. AMIN: NOTHING FROM ME. THANK YOU, YOUR HONOR.

11:02AM 15 THE COURT: ALL RIGHT. MR. GORGI, ANYTHING?

11:02AM 16 MR. GORGI: NO, YOUR HONOR. THANK YOU.

11:02AM 17 THE COURT: ALL RIGHT. THANK YOU. LET ME TURN TO  
11:02AM 18 THE FDA LAWYERS WHO ARE HERE. ANYTHING ELSE YOU WOULD LIKE ME  
11:02AM 19 TO KNOW OR ANYTHING YOU WOULD LIKE TO ADD?

11:02AM 20 MR. WEINFELD: NOTHING FURTHER, YOUR HONOR.

11:02AM 21 THE COURT: ALL RIGHT. THANK YOU VERY MUCH. THANK  
11:02AM 22 YOU FOR BEING HERE. I APPRECIATE YOU COMING OUT. IT'S NICE TO  
11:02AM 23 PUT A FACE WITH A VOICE, SO THANK YOU. IT'S NICE TO SEE YOU.

11:02AM 24 ALL RIGHT. FEBRUARY 10TH, FEBRUARY 10TH.

11:02AM 25 THE CLERK: 10:00 A.M.

11:02AM 1 THE COURT: ALL RIGHT. 10:00 A.M. THANK YOU.

11:02AM 2 MR. LEACH: THANK YOU, YOUR HONOR.

11:02AM 3 MR. DOWNEY: THANK YOU, YOUR HONOR.

11:02AM 4 THE CLERK: COURT IS IN RECESS.

11:05AM 5 (COURT ADJOURNED 11:05 A.M.)

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

CERTIFICATE OF REPORTER

I, THE UNDERSIGNED OFFICIAL COURT REPORTER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

A handwritten signature in black ink that reads "Irene Rodriguez". The signature is written in a cursive, flowing style with a large, decorative loop at the end of the last name.

IRENE RODRIGUEZ, CSR, RMR, CRR  
CERTIFICATE NUMBER 8074

DATED: JANUARY 21, 2020